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Springtime

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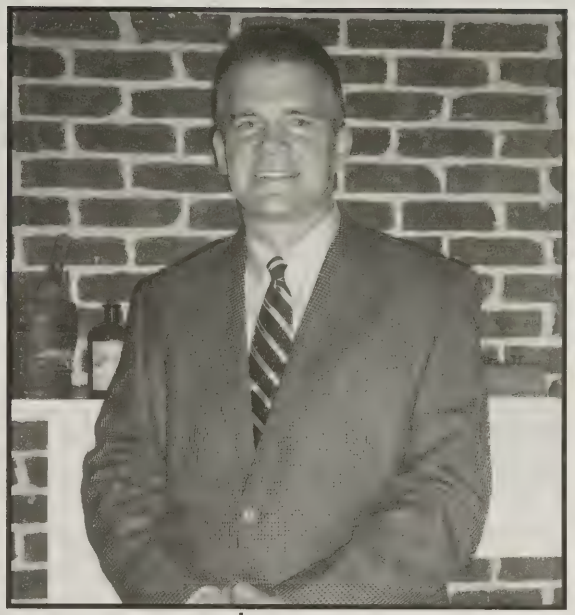
President's Message

Inspire, Engage, Influence...



Frank "Butch" Henderson, P.D.
President

In the last journal I suggested that we would probably have some form of health care reform in place shortly. It didn't happen, and as I write this article we are again preparing for that possibility . Congress is being urged to get it done; I will not make predictions this time. The point for us to keep in mind is that some changes are imminent in health care and that pharmacists truly have a place at the table. We are recognized leaders in patient care and in technology. Our communities and our patients recognize the vital role that pharmacist play in delivering quality products and services to our patients, They recognize our ability to improve health outcomes and to facilitate the overall lowering of health care costs.

We were pleased, despite the snow, to have a record number of pharmacists and technicians at our Mid-Year meeting this past January in Columbia. The meeting featured some very informative, relevant, and cutting-edge programs, and I would like to especially thank Doris Voigt and the convention committee for all of the work in securing speakers and planning such a great event.

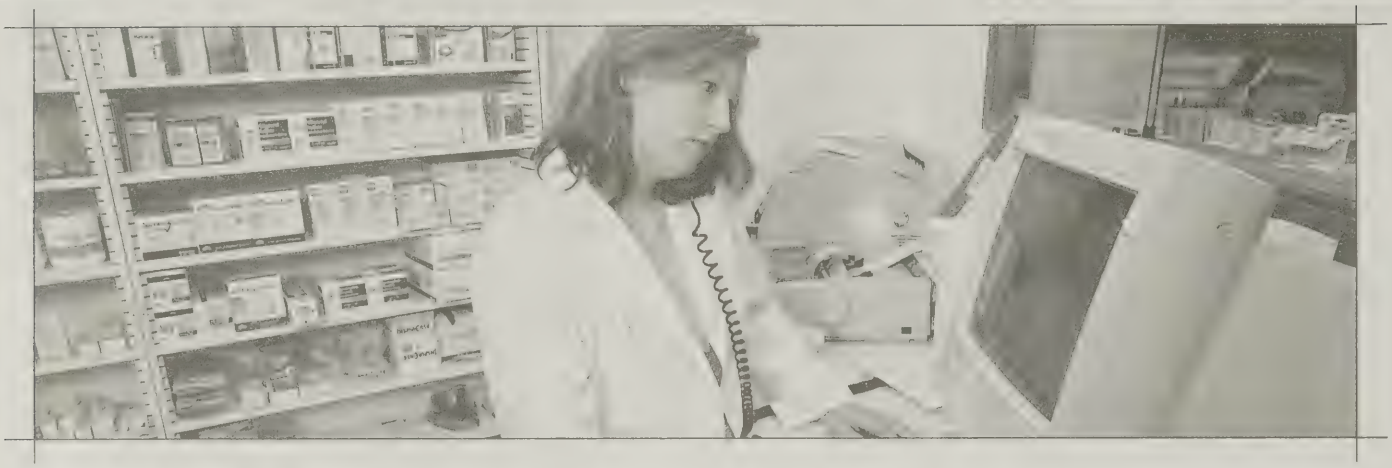
In February, we again saw record numbers of pharmacists, student pharmacists, and technicians in Annapolis for our annual Legislative Day. We are extremely fortunate to have Brian Hose working tirelessly on this program. So much is required to make this day a success and Brian, in between running a successful pharmacy and pushing snow out in Western Maryland, was able to commit countless hours to the success of Legislative Day. We have several pieces of legislation in the process that will enhance the ability of the pharmacists in Maryland to continue to delivery quality care to our patients. I would also like to thank the members of the Maryland Pharmacy Coalition for their strong presence in the lobbying efforts during this session.

I would like to leave you with some thoughts from the national associations this year, the theme from NCPA in October was: Meet...Learn...Succeed. And, this year's APhA meeting's theme is: Inspire... Engage... Influence. These simple concepts can be applied to our daily practice and also to our association. It has been rewarding to see so many pharmacists and student pharmacists in attendance at our meetings. The opportunities to network and learn from each other are invaluable and ultimately will allow us to succeed ,not only professionally, but also in our ability to care for patients. We continue to be one of the most respected and accessible members of the health care community. I would challenge you to find ways to continue to ***Inspire***: inspire your patients to be healthier and more compliant. I would like to challenge us to ***Engage***: engage pharmacists to become more active in the pharmacy community and the associations; engage employers to create opportunities for pharmacists to expand their practices to incorporate the elements of pharmacy care .Those services, which will need to be reimbursed fairly, include immunizations and MTM. And ***Influence***: we can influence our patients and we can influence our communities to be healthier and more responsible with their medications and to look to their pharmacists as their healthcare resource.

Finally, mark your calendars for June 12-15, the Annual Convention in Ocean City will feature great programs, opportunities for networking and social activities, informative CE sessions, a golf tournament on June 11th, crab feast, and much more.

Respectfully, Butch.

Is your pharmacy running *you*?



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Therapeutically Speaking...

Mounting Concerns with Varenicline Result in Update to Product Labeling

Ashley LaFlame, Pharm.D.[1] and Azita Alipour, Pharm.D.[2]
[1] PGY2 Psychiatric Pharmacy Practice Resident (2009-2010), [2] (2008-2009), University of Maryland, School of Pharmacy, Baltimore, MD

Smoking cessation is an uphill struggle for many Americans. In 2007, of the estimated 43.4 million active adult cigarette smokers in the United States, 13.4 million had stopped smoking for at least one day during the preceding 12 months because they were trying to quit.[1] These smoking cessation attempts are most often unassisted and unsuccessful, with a reported probable long-term success rate of about 2-3%.[2] For patients wanting to quit, nicotine replacement therapy (NRT) and bupropion have been long standing therapeutic options with demonstrated efficacy.[3] In May 2006 almost a decade after bupropion received an indication for smoking cessation, the Food and Drug Administration (FDA) approved varenicline (CHANTIX®) for smoking cessation. Varenicline, a novel agent, is a centrally acting partial nicotinic acetylcholine receptor agonist. As a non-nicotinic partial agonist of the $\alpha_4\beta_2$ nicotinic acetylcholine receptors, binding of varenicline leads to a sustained low level partial stimulation of receptor-mediated dopamine release in the mesolimbic system. As a result, varenicline suppresses nicotine craving and withdrawal symptoms while also blocking the rewarding effects associated with increased dopaminergic release following nicotine inhalation.[2, 4]

Preclinical trials of varenicline have demonstrated superiority over placebo for achieving smoking cessation and reducing relapse.[5-9] The most notable side effect identified in these clinical trials was nausea, occurring in 30% of subjects.[4] In order to alleviate and potentially avoid nausea, the medication should be taken with a meal and the dose should be slowly titrated per the manufacturer recommendations. Other frequently reported side effects include insomnia, abnormal dreams, headache, anxiety, depression, emotional disorder, and irritability. Infrequent side effects noted during preclinical trials consist of aggression, agitation, disorientation, dissociation, decreased libido, mood swings, and abnormal thinking.[4, 10]

Initial safety concerns with varenicline therapy were identified during post marketing surveillance. The first two case reports addressing the potential for neuropsychiatric adverse events were published in the August 2007 edition of the *American Journal of Psychiatry*.[11, 12] In the first case, a patient with a past psychiatric history significant for schizophrenia experienced a 5-day psychotic episode after receiving varenicline 2mg/day for 5 days. Prior to the initiation of varenicline, the patient's schizophrenia had been stabilized and controlled with thiothixene therapy.[11] In the second case, a patient with a history of bipolar disorder experienced an acute episode of mania one week after starting varenicline 1mg twice daily. Prior to the introduction of varenicline therapy, this patient's mood had been stabilized with valproic acid therapy.[12] In both of these cases, the neuropsychiatric symptoms resolved after appropriate treatment was given and varenicline was discontinued.[11,12] These cases raised new questions about the safety of varenicline not only in those patients with a history of mental illness, but also in the general patient population. In November 2007, The FDA responded to these safety concerns by releasing an early communication alerting healthcare professionals to the potential risks and recommending increased monitoring for behavior/mood changes at the initiation of varenicline therapy.[13] Establishing causality between the use of varenicline and these reported symptoms is confounded by the symptoms of nicotine withdrawal (increased irritability, frustration/anger, anxiety, dysphoric/depressed mood, difficulty concentrating, and insomnia). While it is arguable that the reported behavioral and mood changes may be associated with nicotine withdrawal, some neuropsychiatric adverse events occurred in people who continued to smoke while taking the medication.[2] As the FDA's review of the issue has progressed, they deemed the association between varenicline and serious neuropsychiatric symptoms increasingly likely resulting in a public

health advisory (February 2008)[14], and revisions to product information (May 2008 and July 2009).[4, 14] The most recent warnings issued in July 2009 required changes in product information for both oral agents indicated for smoking cessation, varenicline and bupropion. These changes called for manufactures to add a black box warning for neuropsychiatric adverse effects and provide a medication guide addressing the previously reported association between varenicline or bupropion use and changes in behavior, hostility, agitation, depressed mood, suicidal thoughts/behaviors, and attempted suicide.[4]

While there have been mounting concerns over the risk of adverse effects associated with varenicline therapy, continued smoking is known to cause serious and potentially fatal health consequences, including an increased risk of heart disease, stroke, cancers, respiratory disorders and complications of pregnancy.[15] In fact, cigarette smoking is reportedly the leading cause of preventable death in the United States accounting for about 443,000 deaths[16] and $157 billion in health care losses annually.[10] These risks associated with smoking must be balanced against the risk of adverse effects associated with medications that can aid in smoking cessation.[3] Ultimately none of the smoking cessation products are benign; however, all of them likely pose less of a long-term health risk than continued smoking.

Given the gravity of the health consequences associated with smoking cigarettes, clinicians should provided education to all patients who are active cigarette smokers. This education should focus on the health benefits of smoking cessation and the common symptoms associated with nicotine withdrawal (irritability, feeling anxious, depressed mood, and trouble sleeping).[3] Additionally, clinicians should thoroughly discuss the benefits and risks associated with each of the available treatment options for smoking cessation in order to actively engage patients in the treatment decisions process.[3] In the instances where varenicline therapy is deemed appropriate, patients and their families/caregivers should be instructed to monitor for neuropsychiatric symptoms including changes in behavior, agitation, depressed mood, suicidal ideation and suicidal behavior both during therapy initiation and maintenance.[4,14] Patients and/or caregivers should be instructed to report such symptoms immediately to their healthcare provider. Those patients with a pre-existing psychiatric illness should be more closely monitored as they may experience worsening of their pre-existing psychiatric illness while taking varenicline. For those who discontinue treatment due to a neuropsychiatric event, continual monitoring is recommended until all symptoms resolve. Health care professions are urged to report all adverse reactions that may be related to the use of varenicline to the FDA through the MedWatch program.[4,14]

Edited by….Dr. Mary Lynn McPherson, Professor, University of Maryland School of Pharmacy

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The Most Widely Used Drug in History

by Viviana Ramirez, Pharm.D. Candidate 2010

Aspirin, acetylsalicylic acid (ASA), is truly a wonder drug that has managed to maintain its popularity and therapeutic usefulness throughout decades. First introduced to the market in 1899 by Bayer Laboratories, Aspirin came about in an effort to maintain the pharmacologic activity of sodium salicylate but without the same unpleasant taste and gastrointestinal discomfort that made it intolerable to most for ingestion. It was first synthesized in its crude form by French chemist Charles Gerhardt in 1853, but was abandoned and later rediscovered by German chemist Felix Hoffman in 1897.

The name Aspirin comes from the combination of the "A" in acetyl chloride, the "spir" in spiraea ulmaria a plant containing salicylic acid, and the "in" was a common ending for medicines during those times. The original dosage form was powder, but in 1904 it was replaced with a stamped tablet to allow exact dosage and prevent adulteration. In the 1920's it was used primarily as a painkiller in patients suffering from rheumatism, lower back pain, and neuralgia. In 1950 Aspirin earned its place in the Guinness Book of Records as the most popular painkiller in the world.

In the early 1970's, a new role for aspirin was discovered thanks to the works of Sir John Vane, who found the main mechanism of aspirin-like drugs to be the inhibition of prostaglandin synthesis. With a better understanding of aspirin's mechanism of action, came research into possible new clinical applications for its use. The first randomized controlled trial of aspirin in the prevention of vascular events was reported in 1974. Since then hundreds of trials have been conducted and helped established aspirin's role in the prevention of major cardiovascular events.

Aspirin's antithrombotic and anti-inflammatory effects are now being looked at for potential benefit in areas such as dementia and cancer. The plausible biological mechanisms for potential cognitive benefit with aspirin therapy include the prevention of multi-infarct lesions or inflammation associated with cognitive decline. Currently Bayer is conducting the *Aspirin to Reduce Risk of Initial Vascular Events* (ARRIVE) trial in hopes to add to the body of evidence in support of aspirin's role in cerebrovascular disease.

Yet another new role for aspirin as a potentially effective chemopreventive agent, particularly in colorectal cancer, has been demonstrated in numerous observational and randomized trials. Through its action on the cyclooxygenase 2 (COX-2) pathway, Aspirin has shown to be effective against the development of colorectal adenomas and cancer. However, the current international consensus calls for further risk-benefit data before a recommendation regarding aspirin therapy for cancer prevention can be made.

In conclusion, although since replaced as drug of choice by newer, more specific medicines for pain and other originally prescribed indications, Aspirin's future is bright with potential expanded uses.

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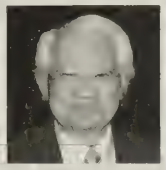
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Pharmacy Time Capsules
2010 (First Quarter)

1985—Twenty-five Years Ago:

- AIDS test for blood approved by FDA in its first major action to protect patients from infected donors.

- The Kroger Company of Cincinnati outbid Rite Aid for the Hook's Drug Stores chain of Indianapolis and combined it with their Super-Rx units.

- First oral drug approved to prevent/reduce recurrent outbreaks of genital herpes Zovirax (Burroughs Wellcome)

1960—Fifty Years Ago:

- 5-year BS implemented as the minimum standard for U.S. colleges of pharmacy.

- Eugene White of Berryville, VA opened an office based pharmacy that stressed relationships with patients and utilized formal patient prescription monitoring.

1935—Seventy-five Years Ago:

- First reports of the clinical effectiveness of Gerhard Domagk's new medicine (Prontosil) for infections appear

- Formulary of the University Hospital, University of Michigan developed by Harvey A.K. Whitney, Sr.

1910—One Hundred Years Ago:

- First Pharmaceutical Syllabus issued providing the basic course of study for the 2-year PhG and providing a more objective basis for licensure examinations and reciprocity.

- Founding of Arizona Pharmaceutical Association

- Phi Delta Chi ratifies the change of its name from Phi Chi to avoid confusion with Phi Chi Medical Fraternity

By: Dennis B. Worthen Lloyd Scholar, Lloyd Library and Museum, Cincinnati, OH

PHARMACY MARKETING GROUP, INC

AND THE LAW

By Don McGuire, R.Ph., J.D.

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NEVADA RULES ON PHARMACIST'S DUTIES

The Nevada Supreme Court has ruled on the case asking whether seven chain pharmacy owners and one independent owner were rightfully dismissed from the civil case, Sanchez v. Wal-Mart Stores, et al. The case arises from a June 2004 car accident caused by Patricia Copening. She was driving along a busy Nevada highway while under the influence of prescription medications. The accident killed one man, Gregory Sanchez, Jr., and injured another, Robert Martinez.

Prior to the accident, in June 2003, the Nevada Prescription Controlled Substance Abuse Prevention Task Force sent letters to 14 Las Vegas area pharmacies informing them that Copening may be abusing drugs. The letter informed the pharmacies that Copening had received approximately 4,500 hydrocodone tablets from 13 different pharmacies during the previous year. She continued to receive multiple prescriptions for hydrocodone-acetaminophen and carisoprodol between June 2003 and June 2004 when the accident occurred. She appeared confused. The police found prescription bottles and loose tablets in the vehicle. She was found to have hydrocodone in her system. She served nine months in jail after pleading guilty to reckless driving.

A civil case was filed by the Sanchez family, Mr. Martinez and his family against Copening, the doctors prescribing for her, and the pharmacies. The district court dismissed the pharmacies because Nevada law did not impose a duty on the pharmacies to take action after receiving the Task Force letter.

The Supreme Court of Nevada reviewed the case and answered two questions; First, did the pharmacy have a duty to act to prevent their patient from injuring members of the general public, and Second, did Nevada law allow third parties to maintain a negligence *per se* claim. The case was decided by a 5-2 margin, with a strong dissent.

The majority and the dissent agreed that under Common Law principles, a person has no duty to control the dangerous conduct of another person or to warn others of the dangerous conduct. There is an exception to this rule however. If there is a special relationship and the harm is foreseeable, there is a duty to act. The majority and dissent diverged on the analysis of whether a special relationship existed in this case because they weren't consistent on which parties form this special relationship. The majority talked about the

relationship between the pharmacy and the victim, while the dissent talked about the relationship between the pharmacy and the patient. The majority notes that the pharmacy had no relationship with the victims and that they were, in fact, unidentifiable prior to the accident. This is an important point in the analysis because it is clear that there is a special relationship between a pharmacy and its patients.

The majority noted that the pharmacy had no requirement to act after it received the Task Force letter. However, they pointed out in a footnote that the regulations had changed since this incident, but declined to opine as to whether the decision would be different because of the rule changes. The ruling in the case was that the pharmacies had no duty to act because the law didn't require them to act and there was no special relationship formed that would require them to act. The majority also ruled that a negligence *per se* claim could not be maintained because the laws in question were not intended to protect against the injuries that the plaintiffs had sustained.

While the pharmacies were dismissed in this case, the case should serve as a wakeup call to pharmacists. The dissent made some strong arguments, and even the majority hinted that the answer might be different under today's laws. The court here said that the pharmacies did not have a duty to act upon information received from the task force, so they never provided guidance as to what a pharmacy should do if it were required to act. This issue is very likely to come up again and the next court could find that the pharmacy was required to act. Prescription drug monitoring programs work by providing information that a single pharmacy or prescriber is unlikely to obtain on their own. In the past, a single pharmacy was usually unaware of all of a patient's activities in acquiring controlled substances and didn't have enough information to take any action. In the present case, the pharmacies were notified that the patient was getting prescriptions filled at 12 other pharmacies around town. It is very possible that this additional information might provide the basis for a court or legislature to make a major change in the law of negligence.

© Don McGuire, R.Ph., J.D., is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

Volume XXVI, No. 4

Community-Acquired MRSA Infections:
A Growing Concern

Thomas A. Gossel, R.Ph., Ph.D., Professor Emeritus, Ohio Northern University, Ada, Ohio and
J. Richard Wuest, R.Ph., PharmD, Professor Emeritus, University of Cincinnati, Cincinnati, Ohio

Goal. The goal of this lesson is to discuss community-acquired MRSA infections, comparing and contrasting them with hospital-acquired MRSA illness.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. recognize the extent and communicability of MRSA infections in the community;
2. select important principles that describe MRSA infections and their treatment including the mechanism of resistance acquired by *Staphylococcus aureus*; and
3. identify specific measures that help limit MRSA infections.

The advent of modern antimicrobial agents in the last century soon met with emergence of resistant organisms that threatened the effectiveness of antimicrobial options. Of the two million hospital-acquired infections each year in the United States, more than half are caused by drug-resistant strains of bacteria, with some intensive care units reporting resistance rates exceeding 70 percent. Drug resistance imposes a considerable impact on patient morbidity and mortality, and is a major economic burden for the nation with annual expenditures projected to be as high as $30 billion. A bacterium of particular concern is *Staphylococcus aureus* (*S. aureus*).

Evidence is mounting that MRSA (methicillin-resistant

Gossel

Wuest

Staphylococcus aureus) acquired from within the community (community-acquired [CA-MRSA]) is a formidable pathogen that is increasing in the United States and worldwide. Many of these community isolates pose a significant threat because they consist of a heterogeneous mix of MRSA strains, some apparently well suited to survival and propagation. CA-MRSA has now emerged as the most frequent cause of skin and soft tissue infections that bring affected individuals to emergency facilities in the United States.

The Changing Face of *Staphylococcus aureus*

Staphylococcus aureus was first described in 1882 by Sir Alexander Ogston, a Scottish surgeon, who noted the pathogen's role in sepsis and abscess formation. Its virulence was not truly appreciated until 1942, when an 82 percent mortality rate was reported among 122 patients with *S. aureus* bacteremia at one New England hospital. *S. aureus*, often referred to simply as "staph," is a widespread bacterium that causes a large variety of infections ranging from mild skin and soft tissue infections such as furuncles (abscessed hair follicles or "boils") and carbuncles (coalesced masses of furuncles), to serious, life-threatening illness such as sepsis and toxic shock syndrome. It is, therefore, one of the most clinically important bacterial pathogens that results in substantial morbidity, even mortality. An estimated 25 to 30 percent of the population is colonized with *S. aureus* (i.e., bacteria are present but are not causing infection). Sites of colonization include the nose (primary site), mucous membranes or breaks in the skin. Colonized individuals are more likely to develop staphylococcal infections; however, many who are colonized remain asymptomatic. Staphylococcal infections occur more often in persons with compromised immune function.

Virtually all *S. aureus* strains were susceptible to penicillin G when it was initially introduced in the early 1940s. By 1944, however, the first reports of penicillin-resistant *S. aureus* strains had appeared. At that time, penicillin resistance was limited to hospital-acquired (nosocomial) infections. The incidence of penicillin-resistant strains of *S. aureus* continued to increase over the next several years, leading to development and introduction in Europe in 1959 of methicillin, a semisynthetic

penicillin specifically designed to withstand development of resistance. Within two years, *S. aureus* circumvented the therapeutic activity of methicillin by altering one of its cell wall proteins. This resulted in resistance to methicillin as well as to all beta-lactam antimicrobials including penicillins, cephalosporins and monobactams, and eventually resistance to many macrolides, clindamycin, and fluoroquinolones. These early reports appeared first in the U.K., followed by other European and Asian countries, and Australia.

Methicillin was introduced in the United States in 1961. Several other "extended" activity penicillins followed. Resistance was reported by 1968. Over the next several decades, sporadic outbreaks of MRSA infections acquired within hospitals and long-term care facilities were reported. It was predicted that by the early 1990s, the incidence of nosocomial methicillin resistance would reach 20 to 40 percent.

Alarming news, however, came in 1999 when the U.S. Centers for Disease Control and Prevention (CDC) released a shocking report detailing four pediatric deaths in the upper Midwest due to CA-MRSA infections. None of the four children had any of the known risk factors for MRSA. Their infections rapidly progressed to pneumonia, sepsis and death. These cases prompted the initial U.S. investigations into what are now described as CA-MRSA infections. Since the initial CDC report, substantial outbreaks have occurred among athletic teams and prison inmates, as well as Native American and pediatric populations. It is now apparent that CA-MRSA illness can occur in otherwise healthy individuals who bear no identifiable risk. Although the exact prevalence is unknown, it appears to be increasing.

Distinguishing CA-MRSA from HA-MRSA

The molecular and antimicrobial resistance profiles of CA-MRSA strains are genotypically distinct from HA-MRSA (hospital-acquired MRSA) strains. Although there is overlap between HA- and CA-MRSA strains, the current CA strains generally remain more susceptible to classes of antimicrobials other than beta-lactams; at present, HA strains are more likely to be resistant. In hospitals, MRSA infections are associated with greater lengths of stay, higher mortality and increased cost of care. The current epidemic strains of CA-MRSA are also characterized by the presence of the PVL (Panton-Valentine leukocidin) gene, which is thought to be a virulence factor for serious infections, and is rarely identified in HA-MRSA isolates. Thus far, CA-MRSA seems to preferentially infect children and young adults. This may be partly explained by the fact that hospital and long-term care facility populations are typically comprised of older patients, versus community populations that contain a broad spectrum of age groups. The CDC has established criteria to distinguish CA-MRSA from HA-MRSA isolates (www.cdc.gov/ncidod/dhqp/ar_mrsa_ca_clinicians.html).

Methicillin Resistance

Methicillin resistance is acquired via a chromosomally incorporated gene termed *mecA* that encodes drug-inactivating enzymes initially named penicillinases and now called beta-lactamases. These enzymes interfere with the binding of beta-lactam antimicrobials to penicillin binding protein 2a. This altered binding protein site with low beta-lactam affinity permits ongoing cell wall synthesis despite the presence of a beta-lactam antibiotic. The term methicillin resistance implies resistance to all beta-lactams. These include all of the penicillin derivatives such as amoxicillin, ampicillin, dicloxacillin, nafcillin, oxacillin and others; cephalosporins; cephamycins, carbapenems; and monobactam antibiotics.

The *mecA* gene is contained in the staphylococcal cassette cartridge (SCC), which is a mobile chromosomal element that aids in successful chromosomal incorporation. Five SCC types (I-V) have been isolated from CA-MRSA. It is now known that the smaller type IV cassette predominates among CA-MRSA strains and indeed its presence distinguishes them from HA-MRSA. Most cases of MRSA infections in the community are related to an increasing community reservoir, rather than a hospital reservoir, of MRSA.

Although alteration of target penicillin-binding proteins is the primary mechanism of resistance to beta-lactam antibiotics, over the years some MRSA strains have developed multiple mechanisms of resistance to several classes of antimicrobials, including macrolides and other erythromycin derivatives, aminoglycosides, fluoroquinolones, tetracyclines, and clindamycin. Glycopeptide antibiotics such as vancomycin have been historically considered to be the only agents to which MRSA strains have not developed resistance. Unfortunately, due to their overuse, MRSA strains have emerged with reduced susceptibility to these agents as well.

Groups at Risk

Though comprehensive epidemiological studies have yet to be conducted, the incidence of CA-MRSA varies regionally. At-risk populations include children (particularly those in daycare centers), homeless persons, intravenous drug users, soldiers, prison inmates and men who have sex with men. Ethnic groups that have been associated with outbreaks include Pacific Islanders, Native American and Alaska Natives, and Pacific and Canadian aboriginals. Competitive sports, specifically football, rugby, wrestling and fencing, are a risk factor with MRSA outbreaks reported among high school, college and professional teams. A lack of personal hygiene and/or poor adherence to basic infection-control principles likely contributes considerably to these outbreaks. Individuals with limited access to

health care and recent or frequent antimicrobial use, or persons in close contact with others who have skin and soft tissue infection, or live in crowded quarters are also at risk. Contamination of the nation's food supply is a potential mode of CA-MRSA spread. In Japan, *mecA*-positive MRSA has been isolated from raw chicken meat. Epidemiologic surveillance is needed to determine whether food sources will emerge as an important mode of transmission.

Clinical Impressions

Roughly 85 percent of CA-MRSA infections involve the skin and soft tissues. Lower respiratory infections account for most of the other infections. Reports associating CA-MRSA as the cause of myositis (inflammation of muscle), osteomyelitis (inflammation of bone marrow) and prosthetic joint infection, to name a few, highlight the large variety of clinical settings and syndromes with which this pathogen has been associated. An even greater diversity of syndromes may become more prevalent with time as general awareness of this pathogen improves.

CA-MRSA should be considered in the differential diagnosis of skin and soft tissue infections, especially in persons at risk or those slow to respond to beta-lactam antibiotics. Although furunculosis and cutaneous skin abscesses are the most common manifestations, simple cellulitis (inflammation of cellular or connective tissue) also can occur. Recurrent infections with transmission to family members, teammates and other close persons occur frequently. A typical reason why ambulatory patients see a physician is the appearance of spontaneous abscesses. Lesions appear red, swollen and warm. They often have a yellow or white center filled with pus and a central point or "head." They may be painful to the touch, and may be suspected to be spider bites by both patients and clinicians, even in areas of the country where spiders capable of causing necrotic skin lesions are not endemic. Such lesions that do not resolve naturally or with therapy should suggest CA-MRSA.

Skin and soft tissue infections account for most morbidity associated with CA-MRSA; mortality is uncommon. However, reports of lethal respiratory infections due to CA-MRSA are increasing. Clinical features of lethal respiratory CA-MRSA infections include leukopenia (decreased leukocytes in blood), hemoptysis (blood-stained sputum), flu-like symptoms, and concomitant furunculosis.

Treatment

Skin and Soft Tissue Infections. The choice of antimicrobial therapy for skin and soft tissue infections depends on a number of considerations, including severity of the infection and whether MRSA is a known or suspected etiologic agent in the area. Additionally, pertinent host factors including immunologic status, allergies and other factors that may impede follow-up must be considered. Beta-lactam antibiotics currently remain antimicrobials of choice for most skin and soft tissue infections in many parts of the country. If CA-MRSA is strongly suspected on the basis of local prevalence data, therapy with an alternative agent is indicated. When feasible, an aerobic bacterial culture should be obtained; its results will dictate which pathogen-specific antimicrobial to use.

For patients with severe skin and soft tissue infections, marked systemic symptoms or comorbid (concomitant, but unrelated infection or disease) conditions, hospitalization with parenteral antimicrobials and appropriate surgical drainage is preferred. Vancomycin remains the initial treatment of choice for serious skin infections when MRSA is suspected, until culture and sensitivity data direct more appropriate therapy. Following clinical improvement, patients may be able to complete their therapy course with oral dosing of an appropriate antibiotic.

Uncomplicated MRSA skin infections may resolve with warm soaks and/or drainage. For small (<5 cm) cutaneous abscesses without significant surrounding cellulitis or systemic symptoms, warm soaks with drainage alone is often sufficient, provided follow-up care is available. Patients with larger abscesses, significant cellulitis, systemic symptoms or serious comorbidities require antimicrobial therapy. Failure to drain abscesses may have dire consequences, even if effective antibiotic therapy is prescribed. Mild to moderate infections that are treated early and appropriately may permit successful outpatient therapy.

Pneumonia. Severe necrotizing pneumonia with or without hemoptysis following an influenza-like illness in persons at high-risk warrants therapy directed against MRSA. Unfortunately, effective antimicrobial options are limited.

Vancomycin (Vancocin) has been used most often, but at routine dosages, it concentrates poorly in alveoli and is inferior to beta-lactam therapy for serious methicillin-susceptible *S. aureus* pneumonia. In one retrospective analysis of a subgroup of patients in a prospective nosocomial pneumonia study, linezolid (Zyvox) was associated with greater cure rates than vancomycin. Whether this is applicable to pneumonia caused by CA-MRSA remains to be seen.

The fulminant nature of these pulmonary infections is presumably caused by PVL toxin. It remains unclear whether more active antimicrobials alone will result in better clinical outcomes. Combination therapies (e.g., vancomycin plus rifampin, TMP-SMX [e.g., Bactrim], or clindamycin) or alternate combinations, although unproven, deserve further investigation. Intravenous immunoglobulin neutralizes PVL toxin *in vitro*, but the clinical relevance of this is unknown.

Prevention of CA-MRSA Outbreaks

Measures to abort and prevent CA-

Table 1
Measures to Limit Spread of CA-MRSA

Personal, caregiver and organizational measures

- Shower daily using soap and hot water
- Wash hands often and/or use sanitation gels
- Cover wounds with dry, clean dressings
- Avoid contact with wound drainage
- Avoid sharing personal items including towels, razors and clothing
- Clean cuts and abrasions with soap and water
- Clean shared equipment routinely (e.g., wrestling mats, benches, athletic equipment)
- Clean and disinfect contaminated surfaces
- Launder contaminated clothes and/or linens in hot water with detergent or bleach
- Avoid contact sports, common whirlpools or saunas if a participant has an open wound
- Use a barrier (e.g., clothes, towels) to cover bare skin when in contact with shared equipment or surfaces (e.g., sauna benches, exercise machines)

Healthcare professional measures

- Use antimicrobials judiciously
- Counsel and educate patients and caregivers about appropriate wound care
- Consider decolonization strategies for recurrent disease or in localized outbreaks in consultation with an infectious disease specialist

Adapted in part from Kowalski TJ, Berbara EF, Osmon DR. *Mayo Clin Proc.* 2005;80:1201-1208.

MRSA outbreaks are important. Education of patients, their caregivers and high-risk populations about preventing and treating CA-MRSA and paying close attention to basic infection-control principles are crucial to preventive strategies. Pharmacists are in a good position to appropriately counsel patients about CA-MRSA. Measures that may be helpful in both CA-MRSA and HA-MRSA infection control are listed in Table 1. A useful hand hygiene fact sheet is available at www.cdc.gov/od/oc/media/pressrel/fs021025.htm.

Careful hygiene interventions appear effective, including daily hot showers, use of antibacterial soaps and hand sanitizers, and appropriate care and coverage of any draining lesions with clean dry bandages. Infected individuals should not share personal items such as towels, razors, and clothing that may facilitate transmission. CA-MRSA wound drainage is highly infectious, and adequate coverage of draining lesions is important. When appropriate coverage cannot be attained, athletes should avoid competition involving physical contact. In addition, targeted sanitation including laundering of clothing, towels and bed linens with hot water and detergent, and regular and thorough cleaning of shared equipment (e.g., wrestling mats, football pads, whirlpools, etc.) may be helpful.

Decolonization. In a recent study of pediatric subjects in the community, 36 percent exhibited nasal carriage of *S. aureus*, including carriage of MRSA in 9 percent of children. This rate represented a significant increase compared with rates in recent years. The rate of *S. aureus* carriage among healthcare workers and hospital staff is also striking, with approximately 6 percent exhibiting nasal carriage of MRSA in some studies.

Decolonization has, therefore, been attempted both to abort outbreaks and prevent disease recurrence, but evidence of effectiveness among outpatients with CA-MRSA strains remains less than convincing. Decolonization strategies have included use of mupirocin (Bactroban) nasal ointment, various combinations of systemic antimicrobials, and chlorhexidine body washes. Mupirocin resistance has been reported in HA-MRSA, but its extent in community strains is unknown. Rifampin eradicates staphylococcal nasal carriage temporarily, but should not be used as monotherapy because resistance to it may develop rapidly. Because the outcome remains uncertain, routine attempts at decolonization of patients with CA-MRSA is not recommended. In persons with recurrent disease, however, it remains a worthwhile intervention. At present, no single intervention at decolonization can be recommended over another.

Summary and Conclusions

CA-MRSA strains are increasing in prevalence and can be highly virulent. Most infections cause skin and soft tissue abscesses that may respond to warm compresses and drainage alone. Several antibiotics with anti-MRSA activity are available. The emergence of vancomycin-resistant strains of *S. aureus* has created a need for agents with expanded coverage. Colonization of nasal passageways and skin with CA-MRSA is likely among persons who have close physical contact with an infected person. Such contacts have a high risk of developing clinical infection. Even after infections are treated, the recurrence rate is high. The most effective and cost-effective intervention remains to be proven. Ideally, a vaccine for at-risk populations should be the most effective intervention, but one that is unlikely to be developed in the near future.

The content of this lesson was developed by the Ohio Pharmacists Foundation, UPN: 129-000-08-004-H01-P. Participants should not seek credit for duplicate content.

Continuing Education Quiz

This month's questions are taken from the article on "Community-Acquired MRSA Infections: A Growing Concern". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230-1701. There is no charge for this quiz for MPhA members (non-members $10.00). The completed quiz for this issue must be received by 4/15/2011. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly.
ACPE# 0129-0144-08-004-H01-P

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. The letter "M" in the term *MRSA* refers to:
a. macrolide. c. minocycline.
b. methicillin. d. mupirocin.

2. The primary site of *S. aureus* colonization is the:
a. feces. c. nose.
b. mouth. d. toes.

3. *S. aureus* circumvented the therapeutic activity of the antimicrobial referred to in Question # by:
a. encapsulating itself with a protective capsid.
b. assimilating it into its own DNA.
c. developing an alternative reproductive system.
d. altering one of its cell wall proteins.

4. Thus far, CA-MRSA seems to preferentially infect:
a. children and young adults.
b. pregnant and lactating females.
c. persons over 70 years of age.
d. immunocompromised patients.

5. All of the following are members of the beta-lactam
group of antibiotics EXCEPT:
a. erythromycin. c. amoxicillin.
b. carbapenems. d. cephamycins.

6. The highest percentage of CA-MRSA infections involve the:
a. bones and joints. c. skin and soft tissues.
b. nose and throat. d. bladder and kidney.

7. Clinical features of lethal respiratory CAMRSA infections include all of the following EXCEPT:
a. blood-stained sputum.
b. concomitant hives.
c. flu-like symptoms.
d. decreased leukocytes in the blood.

8. The initial treatment of choice for serious skin infections when MRSA is suspected is:
a. azithromycin. c. doxycycline.
b. clindamycin. d. vancomycin.

9. All of the following are correct measures to limit spread of CA-MRSA infections EXCEPT:
a. avoiding the sharing of personal items.
b. not covering wounds, allowing them to aerate.
c. showering daily with soap and hot water.
d. washing hands often, and/or use of sanitation gels.

10. Decolonization strategies for MRSA have included use of which of the following antimicrobials?
a. Macrolide c. Minocycline
b. Methicillin d. Mupirocin

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President's Message
Thank You...

Frank "Butch" Henderson, P.D.
President

It has been an honor to have served as President during the past year. It is refreshing to see the number of pharmacists and technicians who are actively engaged in promoting the profession in Maryland. The Maryland Pharmacists Association has been true to its mission of promoting excellence in pharmacy practice, strengthening the profession of pharmacy, and advocating for all Maryland pharmacists.

The Mid-Year Meeting and the Annual Convention were truly indicative of the interest and energy that you, the members, share with the Board of Trustees in promoting and strengthening the profession through educational and networking opportunities. We have had "standing room only" attendees and are already planning for a larger venue for the next Mid-Year.

We continue to ask for your contributions in terms of volunteering to serve on a committee or, simply, sending in your thoughts and comments as to how we can improve the programs that are being offered. One of the goals this year is to continue to engage and involve more of the membership; we will have many opportunities for you to do so. In addition, we would like to find ways to reach out and connect to the different regions in our state, possibly with some local meetings, dinners, or other functions that can help to get pharmacists and technicians together.

One of the more exciting events each year is our annual Legislative Day in Annapolis. The opportunity to advocate for pharmacy has been awesome and very well-received by our legislators. We need more pharmacists to attend and support this event. Every year the student pharmacists are the largest segment and we are very lucky to have the support of the students, faculty, and deans to make this event as powerful as it is. This year we will have three pharmacy schools as we welcome the University of Maryland Eastern Shore School of Pharmacy to join the Schools from the University of Maryland Baltimore and Notre Dame. However, we really need you, as pharmacists many of whom have relationships with the legislators, to make the commitment to become active in this one day event.

It was a great opportunity for the Board of Trustees to assemble for the strategic planning conference earlier this year. A diverse group of leaders within the association was able to share ideas, and under the direction of our good friend Bob Beardsley, to ultimately re-affirm our mission and develop a solid plan for the future growth and direction of the association.

Finally, please consider helping us promote pharmacy by becoming a member of the P3 Program, that recently received with one of the most prestigious awards in pharmacy, the Pinnacle Award from the APhA Foundation. The program is an opportunity for pharmacists to showcase their skills and commitment to healthy patient outcomes in the community. The patients love the program, as do the employers, and I'm certain that other states wish that they had as much success. We are very fortunate to have had the people in place to make this possible but we must sustain the program with trained and dedicated pharmacists. The opportunity to expand to new disease states and reach out to new employers is there. But we need your help, so stay tuned for details on how to become trained and how to get started in this very worthwhile program.

Thank you again for the opportunity to serve as President and keep up the great work that you do every day in your jobs, with your families, and in your communities. I am proud to be affiliated with such great people and look forward to our continued success.

Respectfully, Butch.

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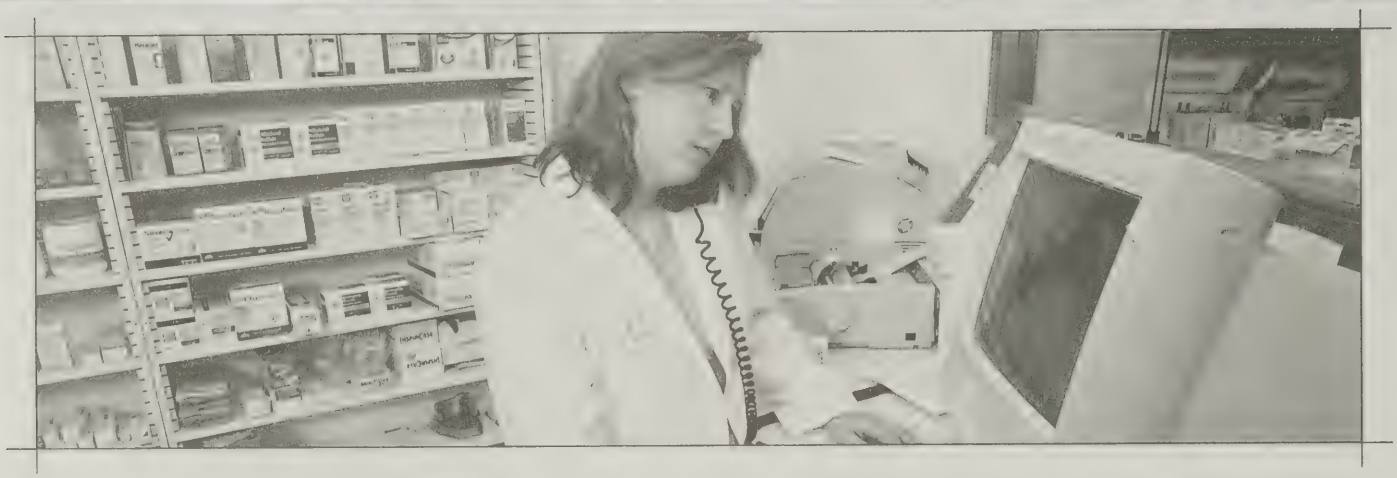

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By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

SPOLIATION OF EVIDENCE

As a pharmacist, you are aware that if you dispense an incorrect medication, you must take care of the patient. This normally includes apologizing for the error, correcting the mistake, and contacting the patient's physician. These are all important, but you may forget that you also need to take care of yourself. If a patient receives an incorrect medication, there is always a chance they could sue you. That is why it is so important to gather and preserve all relevant information about that incident.

The best thing you can do after a dispensing error has occurred is to thoroughly document the situation. It is recommended that you record the following: how the error occurred, the date the error occurred, the date the error was discovered by the patient, the date the error was brought to the pharmacy's attention, the amount of doses the patient believes they ingested, the amount of doses returned to the pharmacy, and the names of anyone you spoke to while resolving the issue. Document all conversations with the patient or the caregiver. Don't use an abbreviated form of documentation. Use complete words and sentences. It may be easy for you to recall all of the details now, but it could be a year or more before a lawsuit is filed. After filling thousands of prescriptions and handling other problems, it may be impossible for you to remember anything about that specific incident. To be safe, all documentation should allow a party who was not involved to fully understand the situation.

It is worth mentioning a second time to document the amount of doses the patient brought back to the pharmacy and preserve the physical evidence. Too often a pharmacist will verify the patient received the incorrect prescription and then dispose of the medication. They have just disposed of a valuable piece of evidence. The number of doses returned to the pharmacy can help establish the maximum number of doses the patient could have ingested. At any time in the future, if the patient claims they took a specific quantity of capsules/tablets, you will be able to confirm or deny this claim with your documentation and the returned prescription vial. Count the tablets and save the bottle. Treat this

as evidence by placing it in an envelope and sealing it with your initials on the closure.

The production of evidence in litigation is governed by the Rules of Civil Procedure.[1] The rules require a party to preserve evidence in a number of situations. It could be in situations of actual pending litigation or when a party is put on notice of a potential claim. It is also a requirement to keep evidence if a party reasonably anticipates that the information might be needed for future reference. As you can see, the requirement to preserve evidence is broad. It can be argued that a patient returning to the pharmacy with incorrect medication that resulted in an injury creates a situation where litigation is reasonably foreseeable. The best practice is to assume this is true and preserve the evidence.

Spoliation is the destruction or significant alteration of evidence in a case. What happens if you don't preserve evidence? The rules also provide the sanctions available when spoliation occurs. These sanctions run the gamut from reprimands, findings of contempt, up to dismissal of a case. Generally, it will take an egregious violation for a court to dismiss or default a case, so it is not very common.

However, it is more common for the court to allow the jury to make a negative inference from the spoliation of evidence. That is, the jury is allowed to presume that the evidence destroyed was more likely injurious to the destroying party's case than it was likely beneficial to their case. This is really a common sense application. People are not likely to destroy things that will be helpful to them. This, of course, is not true in all cases, but what is a jury to do if the evidence is destroyed? The returned prescription might have proven your case, but if you disposed of it, the court will give the jury the spoliation instruction. This instruction can be very damaging to your case and may result in a significant verdict against the destroying party.

The bottom line is you should be able to reproduce or recall details in the future that you would have been able to answer the day the patient presented with the error. If you destroy, dispose of, or do not record some piece of evidence, it could have severe consequences. All of this documentation and preservation is in your best interest. Protect yourself, be complete.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

1. For convenience in this article, we will use the Federal Rules of Civil Procedure as the reference. Each state court has its own rules which may vary from the Federal Rules.

NITROGLYCERIN

by Cynthia Kim, Pharm.D.

HISTORY

The discovery and development of drugs is commonly linked to a series of chance events wherein important advances in knowledge and medicine have subsequently benefited. In the case of nitroglycerin, what appears to have been a chance discovery was actually the result of a series of observations and insights of individual researchers. The story of nitroglycerin sheds light into the progression and evolution of what is now a well-known drug, starting with the chemical synthesis as an explosive in 1846 and its first use in humans in 1846 to the discovery of a useful and effective coronary drug. Its success as an anti-anginal drug can be traced to its homeopathic origins which contributed significantly to its recognition and popularity in conventional medicine. Thus, the history of nitroglycerin is an example of the transfer of knowledge between two otherwise distinct realms of medicine, homeopathic and modern medicine, in the latter half of the 19th century.

A DYNAMITE DISCOVERY

Nitroglycerin was first synthesized in 1847 by the Italian chemist Ascanio Sobrero in Paris. The nitration of glycerol was achieved using a mixture of nitric and sulphuric acid. The reaction is highly exothermic and results in the detonation of nitroglycerin unless the mixture is cooled during the reaction process. Sobero tested the compound and found that it was sweet, pungent, and aromatic; but "great precaution should be used, for a very minute quantity put upon the tongue produces a violent headache for several hours." Following this initial discovery, in 1849, a man known as Constantin Hering who tested nitroglycerin in healthy volunteers and observed that the headache was caused reliably in every individual tested. Hering promoted nitroglycerin as a homeopathic remedy for headache, under the doctrine that "like cures like." As such, nitroglycerin was added to the repertoire of homeopathic remedies.

MEDICINAL USE OF NITRATE

Alfred Nobel joined Pelouze and Sobrero in 1851 and recognized the potential of nitroglycerin. Nobel obtained the first patent on nitroglycerin as an industrial explosive. Alfred Nobel while working on explosives, attempted to make nitroglycerin safer to handle. He found that nitroglycerin is stabilized by the addition of kieselguhr (a siliceous deposit; also known as diatomaceous earth), and calls this mixture dynamite. In 1879, William Murell in an article published in the Lancet described his successful use of nitroglycerin in four patients with angina pectoris. He used nitroglycerin because of the similarity between its mode of action and that of amyl nitrite, which in 1864 had been reported to be effective in angina pectoris by Thomas Lauder Brunton. Brunton made a number of observations on angina pectoris appearing in the Lancet:

> …few things are more distressing to a physician than to stand beside a suffering patient who is anxiously looking to him for that relief of pain which he feels utterly unable to afford…the regret he feels…serves as a constant and urgent stimulus in his search after the causes of the pain and the means by which it may be alleviated.[1]

It occurred to Brunton that if one could lower the pressure in the vessels, one would very likely alleviate the pain. Brunton applied five to ten drops of nitrite on a cloth and gave it to the patient to inhale. The effect took place almost immediately—between 30-60 seconds the patient's face became flushed, the pulse rebounded and the pain instantaneously disappeared. Brunton astutely noted that if the remedy was used for a long period of time, the dose required an increase before the same effect was produced; an allusion of nitrate tolerance.[2] In the following years, Brunton and his colleagues published widely on the effects of the compound. They looked particularly for compounds that had a slower but more lasting action than amyl nitrite and tested extensively on various forms of nitromannite. Brunton based research endeavors on Constantin Hering's initial discovery of nitroglycerin as a homeopathic remedy for headaches. Brunton's studies culminated in the establishment of nitroglycerin as an effective treatment for the relief of angina pain.[3] However, the discovery of the mechanism of action was to wait for another 80 years.

DEVELOPMENTS IN THE 20TH CENTURY

Since 1879, nitroglycerin pills have been a standard treatment for angina and heart attacks, but it wasn't until the 1970's that researchers understood that the body converts nitroglycerin into nitric oxide, a messenger molecule that tells the smooth muscles surrounding blood vessels to relax. At this time, a pharmacologist Ferid Murad and his colleagues examined the effects of various vasodilator molecules, including nitroglycerin, and noted that each affected guanylate cyclase activity.[4] They demonstrated that soluble guanylate cyclase from rat liver and bovine smooth muscle was stimulated by the nitrite-containing compounds causing a subsequent increase in cGMP which, in turn, brought about vasodilation. The pharmacologists did not understand the mechanism of this increase but proposed that cGMP activation may occur via the formation of NO because the gas also increased guanylate cyclase activity. The idea that a gas could regulate smooth muscle function was a novel one, and Murad speculated that hormones and other endogenous factors may also play an indirect role and act through NO.[5] These initial discoveries and insights gave rise to a new era of the study of nitroglycerin exploring its mechanism of action and vasodilatory effects.

CONCLUSION

Nitroglycerin belongs to a group of drugs called nitrates, which includes many other nitrates such as isosorbide dinitrate (Isordil) and isosorbide mononitrate (Imdur).[7] Nitroglycerin comes in various dosage forms including tablets, spray, or patches. Nitroglycerin is used medically as a vasodilator to treat heart conditions, such as angina and chronic heart failure. It is one of the oldest and most useful drugs for treating or preventing attacks of angina pectoris from ischemic heart disease. Angina pectoris is caused by an inadequate flow of blood and oxygen to the heart.[8,9] The heart muscle must produce and use energy in order to be able to pump blood through the lungs and into the arteries.

In the article on the history of nitroglycerin, Marsh and Marsh concluded: "Had not the early workers experienced headache and flushing, nitroglycerin may never have entered the pharmaceutical world; it would have remained a useful, if not destructive, material in the hands of the military." Interestingly, however, nitroglycerin entered the pharmaceutical world in 1879 because of the similarity in action with that of amyl nitrite for relief of angina.[6] Today, nitroglycerin induced headache has been a clinical problem that somewhat limits its use as an effective anti-anginal medicine.

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Therapeutically Speaking...

Over the Counter Agents for Seasonal and Perennial Allergic Conjunctivitis in Children

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Allergic conjunctivitis is an inflammatory response of the conjunctiva following exposure to allergens which causes itching, tearing, edema of the eyelids and watery discharge.[1,2,3] Ocular allergies affect up to 40% of the general population[1,4] and allergic conjunctivitis is more common in patients with other allergic etiologies such as atopy, asthma, eczema, hay fever, food allergies or other allergies.[4] Concomitant conjunctiva symptoms are often considered to be a minor annoyance and are underreported by patients with allergic rhinitis and/or asthma; thus, the association between rhinitis and conjunctivitis is largely underestimated in epidemiologic studies.[4] Allergic conjunctivitis can be further classified as seasonal or perennial, with each having different triggers.[3,5,6] It is important for pharmacists to distinguish between the two clinical forms of allergic conjunctivitis, to best provide appropriate education and treatment recommendations.

Assessing Patient Presentation and Making Triage Decisions

Seasonal allergic conjunctivitis often accompanies allergic rhinitis and is most commonly triggered by outdoor allergens such as ragweed, grasses or tree pollens.[5,7] Perennial allergic conjunctivitis is triggered by allergens which are present throughout the year such as dust mites, animal dander, molds, cockroaches, and second-hand smoke.[5,7] The dominant symptoms of allergic conjunctivitis are ocular itching and erythema, which often present bilaterally and do not typically affect a child's vision. Other ocular symptoms include watery discharge, production of stringy whitish mucus, swelling and erythema of the conjunctiva with possible involvement of the eyelids.[1] Non-allergic causes, viral, bacterial, or non-specific origins of conjunctivitis exhibit similar symptoms as allergic conjunctivitis, however, these generally do not involve both eyes and discharge is more purulent.[1-4] Referral to a pediatric ophthalmologist or pediatrician is appropriate if one or more of the following symptoms is present: ocular pain, stinging/burning sensation, purulent discharge, symptoms that start in one eye then progress to both eyes, or changes and/or blurring of vision. Safety and efficacy of most over-the-counter products have not been established in very young children therefore, children less than 3 years of age should consult with their pediatrician.

Approaches to Therapy

Primary treatment of allergic conjunctivitis includes avoidance of allergens, application of cold compresses, and dilution of the allergen with artificial tears or ocular lubricants.[1,7] When avoidance of allergens is not possible, oral or topical antihistamines can be utilized and in some cases short-term use of ocular over the counter (OTC) topical decongestants or a mast cell stabilizer may be warranted.[2,3] Allergen-specific subcutaneous immunotherapy is reserved for children who have failed all non-pharmacologic and pharmacologic options.[2,3] Due to safety concerns and difficulties in performing serial injections of allergens over a period of months to years, allergen-specific subcutaneous immunotherapy is not recommended in children less than 5 years of age[1].

Non-pharmacological Prevention and Treatment

Non-pharmacologic options to prevent and manage children with allergic conjunctivitis consists of educating the family and the child about the nature of the disease and avoiding exposure to common allergens, known triggers, and respiratory tract irritants (tobacco smoke, dust, chemicals).[1-3,7]

Avoidance of allergens involves removing or containing the offending allergen.[1,7] Techniques to control perennial allergens include: removal of dust collectors (heavy drapes, upholstered furniture & stuffed animals); vacuuming and dusting frequently when the child is not in the room; use of airtight, allergy-proof plastic covers on mattresses, pillows and box springs and washing bedding and stuffed animals every 7-14 days. If possible, remove carpeting; avoid the use of ceiling fans; maintain low humidity indoors to control the amount of dust mite and molds in the home and keep the child away from damp or water-damaged areas of your home. Provide a smoke-free environment for your child and, if you must smoke, do so outside. Immediately after smoking, change your clothes and wash your hands to remove the allergens from second-hand smoke. Also, keep pets out of the house. If this is not possible keep the pet out of the child's bedroom and bathe the pet weekly. One technique to control seasonal allergens is covering air vents with HEPA filters to collect airborne allergens such as pollens and ragweed; however, HEPA filters are not useful for collecting dust mites or molds. Another technique to control seasonal allergens is to limit outdoor activities and to keep windows closed in the car and at home.[7]

The use of a cold compress helps to treat pruritus and edema by providing symptomatic relief. Simply wet a

clean wash cloth, ring the cloth out so that it is damp and not dripping, and lay the wash cloth over the child's eyes. It is best to have the child lay on the couch or on their bed when applying a cold compress. In order to prevent further complications, such as an infection in the eye, keep the wash cloth clean. If the child places the cloth in their mouth, obtain a new cloth or rinse the old one prior to placing back on the eye(s). The cold compress can be used as long as the child is experiencing relief and desires to lay with the cloth over their eyes.[1,7]

OTC Pharmacologic Treatment

Over the counter treatment options for children with allergic conjunctivitis are limited to artificial tears, optical lubricants, topical and systemic antihistamines, topical decongestants, antihistamine/decongestant and antihistamine/mast cell stabilizer combination products (Table 1).[1,2,6-8]

Optical lubricants or artificial tears containing hydroxypropyl methylcellulose, propylene glycol, and/or glycerin, are safe to use in children and may help dilute allergens from the eyes. These agents are well tolerated and can be used 3-4 times daily. Artificial tears can be used at any age. The preservative free agents are preferred in patients less than 1 year of age.[1]

Antihistamines

Ophthalmic antihistamines relieve the symptoms of hyperemia, tearing, and itching due to inflammatory response of histamine release. These ophthalmic antihistamines can be used in patients 3 years of age or older. There are no single agent ophthalmic antihistamine products available over the counter; however, there are systemic antihistamines available over the counter that can be used to control allergic rhinoconjunctivitis. First-generation systemic H_1-antihistamines have central nervous system (CNS) side effects and anticholinergic

Table 1[7,8]: OTC Ophthalmic Agents for Allergic Conjunctivitis

Drug	Trade Name	Strength	Dose	Pediatric Use
Optical Lubricants				
Artificial tears	Various products		1gtt TID-QID prn	≥3 years*
Antihistamine agents				
	There are no single agents available over the counter			
Decongestants				
Naphazoline	Alerest, Clear Eyes, Degest2, Naphcon, Allergy Drops	0.012%	1-2 gtt up to QID prn	--
	Vaso Clear, Vaso Clear A	0.02%		
	Comfort Eye Drops	0.03%		
Oxymetazoline	Visine L.R.	0.025%	1-2 gtt Q6H prn	≥6 years
Phenylephrine	AK-Nefrin, Relief, Zincfrin	0.12%	1-2 gtt up to QID prn	--
Tetrahydrozoline	Murine Plus, Tetrasine, Visine Allergy Relief, Visine Moisturizing	0.05%	1-2 gtt up to QID prn	≥6 years
Antihistamine (selective H1-antagonist) Mast cell stabilizer				
Ketotifen	Zaditor, Alaway, Zyrtec Itchy Eye Drops, Claritin Eye	0.025%	1 gtt every 8-12 H (max 2 doses/day)	≥3 years
Decongestant/Antihistamine				
Naphazoline/Pheniramine	Naphazoline plus, Naphcon-A, Visine-A	0.025%/0.3%		≥6 years
Naphazoline/antazoline	Opcon-A Vasacon-A	0.027%/0.3% 0.05%/0.5%		≥6 years

*Used in patients < 3 years if advised by a physician

effects that can cause paradoxical hyperactivity, insomnia, irritability and wheezing in infants and young children. Newer, second generation H_1-antihistamines exhibit less of the CNS side effects and are safer in the treatment of concomitant allergic rhinitis and conjunctivitis in children (Table 2).[2,3]

The most common side effects of cetirizine in children are drowsiness, dry mouth, stomach pain, and difficulty sleeping. The most common side effects of loratadine are headaches, dry mouth, and discolored urine. Both agents can cause photosensitivity reactions, so remind patients to use sunscreen regularly. These agents can be used by patients starting at 6 months or 2 years of age, depending on the agent. They are usually dosed once daily and are generally well tolerated.

It is recommended to initiate both ophthalmic and systemic antihistamine agents for children with severe allergic rhinoconjunctivitis. This allows the ophthalmic antihistamine to provide immediate relief while waiting for the systemic antihistamine to control and prevent the symptoms. Children often experience stinging or burning with ophthalmic preparations and usually prefer systemic antihistamines for controlling their allergic rhinoconjunctivitis. Fortunately, the ophthalmic preparation is only needed for the first 3-5 days, and the systemic antihistamine should be continued as long as symptoms or allergens are present. [1-3,6,7]

Decongestants

Decongestants cause vasoconstriction and reduce symptoms of conjunctiva hyperemia and edema; however, they do not address the underlying allergic or inflammatory response. Ophthalmic decongestants can be used to in patient's ≥ 6 years of age. These agents increase intraocular pressure; therefore, are contraindicated in patients with narrow angle glaucoma. Prolonged use of topical decongestants can result in rebound hyperemia and inflammation so use of these agents is limited to 72 hours. The most common side effects associated with ophthalmic decongestants include rebound dilation and in rare cases, development of acute narrow angle glaucoma.[1,7]

Table 2 [9]: OTC Systemic Antihistamines for Allergic Conjunctivitis in Pediatrics

Drug (Trade Name)	Strength and Formulation	Dose
Loratadine (Claritin)	Tabs 10 mg Chewable 5 mg Disintegrating tabs 5, 10 mg Syrup 1mg/1mL (480 mL)	2-5 yr: 5 mg PO daily ≥6 yr: 10 mg PO daily
Loratidine + pseudoephedrine (Claritin-D 12Hr, or 24Hr)	5 mg + 120 mg PE (12Hr) 10 mg + 240 mg PE (24Hr)	≥12 yr: 1 D-12Hr tab BID or 1 D-24Hr tab daily
Cetirizine (Zyrtec)	Tabs 5, 10 mg Chewable 5, 10 mg Syrup 5mg/5mL (120,473 mL)	6 mo - < 2 yr: 2.5 mg PO daily *(max 2.5 mg Q12Hr)* 2-5 yr: 2.5 mg PO daily *(max 5 mg/24Hr)* ≥6 yr: 5-10mg PO daily
Cetirizine + pseudoephedrine (Zyrtec-D 12Hr)	5 mg + 120 mg PE	≥12 yr: 1 PO BID

Combination Products

Combination products for allergic conjunctivitis are extremely effective. The combined use of an antihistamine and a decongestant agent is more effective than the use of either agent alone. The most effective combination for managing allergic conjunctivitis topically is an agent with dual antihistamine and mast cell stabilization, which has additional anti-inflammatory effects that inhibit release of eosinophil and reduction of chemotaxis through mast cell stabilization prevents histamine release from mast cells. Ketotifen is the only over the counter topical agent with antihistamine and mast cell stabilization properties. This agent is administered twice daily and is preferred over other ophthalmic agents that are used four times a day. Ketotifen can be utilized in patients >3 years of age. This agent is generally well tolerated; however, the most common side effects are burning with administration, dry eyes, itching of the eyes, inflammation of the cornea and possible eye discharge. [3,6,7]

Counseling Points

As the pharmacist, you should educate patients and their caregivers on disease management including non-pharmacologic prevention and treatments. For recommended pharmacologic treatments, explain the dosing frequency and common adverse events that should be expected. In general, ophthalmic agents cause burning or stinging with administration. This discomfort can be

minimized by refrigerating the ophthalmic medication. All OTC ophthalmic agents are used for short-term symptom relief only. If symptoms persist after 72 hours of use, the patient or caregiver should consult a pediatrician.

The patient and caregiver should also be counseled on how to administer ophthalmic drops. Tell the patient or caregiver to wash their hands and remove contact lenses before applying eye drops. Most ophthalmic agents contain the preservative benzalkonium chloride, which is known to permeate contact lenses; therefore, remove contact lenses prior to instilling the ophthalmic preparation and wait 10-15 minutes before placing the contact lens back in the eye. For individuals with allergies that wear contact lenses, 1-day disposable lenses are the preferred type of lens to help manage their allergic conjunctivitis.[1]

Check the expiration date, clarity and color of the ophthalmic solution to ensure there is no change from the original formulation. Discard the product if it has expired, changed color, or is cloudy. Instruct the patient to tilt their head back, look up and pull down the eyelid to make a pouch, instill a drop into the pouch, then close the eyes while applying light pressure with a finger to the lacrimal sac for 1 to 2 minutes after installation. This prevents the medication from draining away from the eye. For young children that may resist the instillation of the ophthalmic preparation, there are a couple of useful techniques that will help to ensure safe administration of the medication. Have the child lay down on a couch or bed. If two caregivers are available have one hold the child in place by stabilizing the head while the second caregiver pulls down the eyelid to make a pouch and instills the ophthalmic drop. If only one caregiver is available do the following: if the child is an infant, swaddle the baby to stabilize or while the child is lying down with their arms folded in their lap use one arm to stabilize the child's body. The hand on this arm is used to form a pouch in the lower eyelid. With the other arm, hold the forehead still and use the hand on this arm to instill the ophthalmic preparation. The purpose of using the hand on the arm holding the forehead for instillation is that the ophthalmic bottle will move with the child and should not cause injury to the eye with undesired movement(s) of the child. Do not touch the top of dropper bottle to eye, fingers, or any other surface; this will avoid contamination of the eye dropper.

Summary

Allergic conjunctivitis is an inflammatory response that is exacerbated by allergens and is more common in patients with other allergic etiologies. Fortunately, allergic conjunctivitis does not cause problems with the function of the eye; however, the pruritus, erythema and watery discharge can be an annoyance. The primary treatment of allergic conjunctivitis includes avoidance of allergens, application of cold compresses, and dilution of the allergen with artificial tears or optical lubricants. Secondary treatment is oral or topical antihistamines and, in some cases, short-term use of an OTC topical decongestants or a mast cell stabilizer may be warranted. Allergen-specific subcutaneous immunotherapy is reserved for patients that fail both non-pharmacologic and pharmacologic therapy. There are multiple agents available over-the-counter to treat allergic conjunctivitis in children; however, in patients less than 3 years of age, the caregiver should consult a pediatrician. Systemic second-generation antihistamines are preferred over ophthalmic agents in treating symptoms of allergic conjunctivitis due to common complaints of stinging and burning and the need for long term control. Topical ophthalmic antihistamines and mast cell stabilizers can be added to oral anti-histamines for short-term control while waiting for the onset of action of the systemic antihistamine. In addition to making recommendations for prevention, management, and treatment of pediatric allergic conjunctivitis, it is vitally important to counsel the patient or caregiver on the appropriate administration techniques of the ophthalmic preparations.

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Autism and Its Treatment: A Primer for Pharmacists

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Goal. The goal of this lesson is to explain autism with focus on its pathogenesis, clinical characteristics and confirmation, and treatment.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. recognize historical events concerning autism, and differentiate each component of the autism spectrum disorders from one another;
2. select important principles that characterize autism and the principles that govern its clinical confirmation and management; and
3. identify specific nonpharmacologic and pharmacologic measures that are reported to modify signs and symptoms of autism.

Autism (autistic disorder) is a complex, chronic and serious neurodevelopmental disorder that affects normal functioning of the brain, impacting development in the areas of social interaction and communication skills. The most common of the pervasive developmental disorders, autism affects an estimated one in 150 births in the United States. With the number growing at a startling rate of 10 to 17 percent per year, its prevalence could reach four million Americans within a decade. Occurring in all racial, ethnic and socioeconomic groups, autism is four times more likely to occur in males than in females. Additional information on autism can be found in the online resources listed in Table 1.

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Background

In 1943, child psychiatrist Leo Kanner of the Johns Hopkins Hospital published the first description of "autistic disturbances of affective contact." Kanner thus introduced the term *infantile autism*, or *autism* into the English language, which defined three symptom patterns: (1) abnormal development of social reciprocity; (2) failure to use language for communication; and (3) desire for sameness, as seen in repetitive rituals or intense circumscribed interests – symptoms that were later termed *Kanner's triad*.

About this same time, Austrian pediatrician Hans Asperger, based on his study of 400 children, described a milder form of the disorder that became known as *Asperger's Disorder* (*Asperger Syndrome*).

Autism is listed in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision (DSM-IV-TR), the primary diagnostic reference for mental health professionals in the United States. It is one of the five pervasive developmental disorders (PDDs), more commonly referred to as autism spectrum disorders (ASDs). Each disorder is characterized by varying degrees of impairment in social interactions, communication skills and restricted, repetitive and stereotyped patterns of behavior. (Table 2) It is not uncommon for more than one of these disorders to coexist in the same family.

Table 1
Representative sources for information on autism

The American Academy of Pediatrics	www.aap.org
The Autism Society of America	www.autism-society.org
Autism Speaks, Inc.	www.autismspeaks.org
First Signs, Inc.	www.firstsigns.org
The Organization for Autism Research	www.researchautism.org
National Library of Medicine and the National Institutes of Health	www.nlm.nih.gov/medlineplus/print/autism.html
National Institute of Mental Health	www.nimh.nih.gov
National Institute of Child Health and Human Development	www.nichd.nih.gov

Table 2
Major characteristics of pervasive developmental disorders

Disorder	Age at onset (months)	Major characteristics
AD	<36	social and communication skills impairment; stereotyped, repetitive/restrictive behavior and interests
PDD-NOS	variable	symptoms not meeting other diagnoses; frequently a milder form of autism; also known as atypical autism
Asperger's disorder	>36	impaired social interactions and restricted interests; delay in motor skills; preservation of early language skills; limited conversational abilities
CDD	>24	normal early development followed by deterioration in social skills, language, behavior, bowel/bladder control and play
Rett syndrome	5-30	progressive developmental disorder with normal early infancy, followed by loss of fine and gross motor skills, language skills, interests, and social interactions; appearance of characteristic hand-wringing movement and muscle-wasting

AD = autistic disorder; PDD-NOS = pervasive developmental disorder-not otherwise specified; CDD = childhood disintegrative disorder

Adapted from Stachnik JM, Nunn-Thompson C. Ann Pharmacother. 2007.41;626-634

Pathogenesis

Although there is no known single cause for autism, it is generally accepted that it follows some abnormality in brain structure or function. Brain scans reveal differences in the shape and structure of the brain in children with autism compared to those without.

Research is ongoing in investigating possible links between heredity, genetics and medical pathology. There appears to be a pattern of autism or related neurological disabilities in many families.

Medical researchers have identified a variation in a gene that may increase the risk for developing autism, especially when the variant is inherited from mothers rather than fathers. The gene, CNTNAP2, encodes a protein that facilitates communication between brain cells through chemical signals and appears to play a role in brain cell development. Inheriting the gene variant does not imply that a child will inevitably develop autism; rather, it means that a child may be more vulnerable to developing the disease.

Other research suggests that a cluster of unstable genes may interfere with normal brain development, resulting in autism. Pregnancy or delivery problems and environmental factors (e.g., viral infections, metabolic imbalances and exposure to environmental chemicals during pregnancy) are also being studied.

Is there a causative role for vaccines? Many studies over the years have looked at the possibility that vaccines are a cause of autism. Autistic characteristics have been described in some children within a few weeks of receiving a vaccine. Until 1999, vaccines intended for infants to protect them against diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b (Hib), and hepatitis B contained thimerosal (a mercury-based preservative). Today, with exception of some influenza vaccines, none of the preparations used in the United States to protect preschool-aged children against 12 infectious diseases contain thimerosal. The MMR (measles, mumps, rubella) vaccine, varicella (chickenpox), inactivated polio, and pneumococcal conjugate vaccines do not and never did contain thimerosal.

The U.S. Institute of Medicine (IOM) conducted a thorough review on the issue of identifying a possible link between thimerosal and autism. The IOM report, released in May 2004, stated that there was no link. At this time, there is no conclusive scientific evidence that any component of a vaccine or combination of vaccines causes autism.

Characteristics

Characteristics (i.e., signs/symptoms) of autism may be evident as early as four months of age. In a few cases, after developing normally, a child regresses into autism. Clinically, neurological abnormalities usually dominate the symptomatology. At the same time, it is emphatically true that intelligence diversity is a major aspect of autism. It has been reported that while approximately three-fourths of patients with autism may be mentally retarded, the IQs of persons with autism may range from severe impairment to intellectually gifted.

Impaired social interaction is the hallmark feature of autism. Table 3 lists common characteristics.

Parents are usually the first to notice symptoms of autism. Early in infancy, a baby with autism may be unresponsive to people or focus intently on one item to the exclusion of others for long periods of time. A child with autism may appear to develop normally for a period, only to withdraw and become indifferent to social interaction.

They may fail to respond to their name and often avoid eye contact with other people. They have difficulty interpreting what others are feeling because they don't understand social cues, such as tone of voice or facial expressions, and they don't watch other people's faces for clues about appropri-

ate behavior. They lack empathy toward others.

Many children with autism engage in repetitive movements such as rocking their head or torso and twirling their hair between fingers, or in self-abusive behavior such as biting or head-banging. They also tend to start vocalizing later than children without autism. Some speak in a high-pitched, or flat, robot-like voice, or in "sing-song" fashion (regular or monotonous rising and falling intonation) about a narrow range of favorite topics.

Many children with autism have an increased threshold to pain, but are abnormally sensitive to sound, touch, or other sensory stimulation. These reactions may contribute to behavioral symptoms such as resistance to being cuddled or hugged.

Children with autism appear to be at higher risk for certain comorbid (concomitant but unrelated) conditions, including fragile X syndrome (the most common inherited form of mental retardation) and tuberous sclerosis (a rare, genetic disorder that causes benign tumor growth in the brain and other vital organs), as well as epileptic seizures, Tourette syndrome (characterized by presence of multiple physical [motor] tics and at least one vocal [phonic] tic), learning disabilities, and attention deficit disorder. For reasons that remain unclear, about one-third of children with autism develop epilepsy by the time they reach adulthood. While persons with schizophrenia may show autistic-like behavior, symptoms usually do not appear until their late teens or early adulthood. Most persons with schizophrenia also experience hallucinations and delusions, neither of which are associated with autism.

Autism symptoms often improve with treatment and with age. Some autistic children can lead normal or near-normal lives as they grow older. Children whose language skills regress early in life, usually before three years of age, appear to be at risk of developing epilepsy or seizure-like brain activity. Some children with autism may become depressed or experience behavioral problems during adolescence.

Persons with autism score consistently low on instruments that measure life skills. The life outcomes of autistic adults range from complete dependence on others to (rarely) successful employment. People with autism typically die early, with death most often coming from seizures, nervous system dysfunction, drowning or suffocation (at a rate exceeding three times the general population). As mentioned earlier, epilepsy occurs in at least one-third of persons with autism. The death rate due to epilepsy is approximately 24 times higher than that of epileptic patients without autism.

Confirmation of Autism

There is no medical test for autism. Physicians rely on a core group of behaviors to diagnose autism:

- difficulty in making friends with peers;
- inability to initiate or sustain conversation with others;
- impairment or absence of imaginative and social interaction;
- unusual, stereotyped or repetitive use of language;
- patterns of interest that are abnormal in intensity or focus;
- preoccupation with a particular object or subject; and
- rigid adherence to established routines or rituals.

While some screening instruments rely solely on parental (or caregiver's) observations, others rely on a combination of notes from both parent and physician. Since autism is a complex disorder, a comprehensive evaluation requires a multidisciplinary team including a neurologist, psychiatrist, psychologist, speech therapist and other professionals who have experience in diagnosing children with ASDs. Team members will conduct a thorough neurological assessment and in-depth cognitive and language testing.

Autism can often be detected as early as 18 months. Increases in the number of autism cases in the United States may be the result of improved diagnosis and changes in diagnostic criteria.

Differential Diagnosis. Children with some symptoms suggestive of autism, but neither qualitatively nor quantitatively sufficient to permit a diagnosis of classical autism, may be diagnosed with pervasive developmental disorder-not otherwise specified (PDD-NOS) (Table 2). Children with autistic behaviors whose language skills are well developed may be diagnosed with Asperger's disorder. Children who develop normally, and then suddenly deteriorate between three and 10 years of age and show marked autistic behaviors, may be diagnosed with childhood disintegrative disorder (CDD). Girls with autistic symptoms may be suffering from Rett syndrome, a gender-linked genetic disorder characterized by social withdrawal,

Table 3
Common characteristics of persons with autism

A child or adult with autism might:

- not play "pretend" games
- not look at objects when another person points at them
- not have an interest in others
- avoid eye contact
- want to be alone
- have trouble understanding other people's feelings or talking about their own feelings
- prefer not to be held or cuddled
- appear to be unaware when other people talk to them but respond to other sounds
- be very interested in people, but not know how to relate to them
- repeat or echo words or phrases
- have trouble expressing their needs using words or motions
- repeat actions over and over
- have trouble adapting to a changing routine
- have unusual reactions to the way things smell, taste, look, feel or sound
- lose skills they once mastered

Adapted from www.cdc.gov/ncbddd/autism/actearly/autism.html

regressed language skills and hand wringing.

Treatment

Although treatment has improved greatly over the past several decades, there is neither a cure for autism nor single approach to therapy. The primary goals are to minimize the core features and associated deficits, maximize functional independence and quality of life, and alleviate family distress. Options may include behavioral and communication measures, drug therapies and complementary approaches.

Behavioral and Communication Measures. Numerous programs target the range of behavioral, social and language difficulties characteristic of autism. Some focus on reducing problem behaviors and teaching new skills. Others focus on teaching children how to communicate more effectively with other people or how to act appropriately in social situations.

Drug Therapies. At present, there is no medication that directly improves the core signs of autism. However, some can help control individual symptoms. Agents most commonly employed in autism include antidepressants (especially SSRIs), used in 20 to 25 percent of patients; neuroleptics (especially second-generation antipsychotics), 10 to 15 percent; stimulants, 10 to 15 percent; alpha agonists, 10 percent; and anticonvulsants, 5 to 10 percent.

Risperidone. The FDA approved risperidone (Risperdal) for the symptomatic treatment of irritability in autistic children and adolescents. The targeted behaviors under the general heading of irritability include aggression, deliberate self-injury, temper tantrums and quickly changing moods. No restrictions on prescribing or use in autism have been put into place to-date.

Risperidone's effectiveness in the symptomatic treatment of irritability associated with pediatric autistic disorders was established in two eight-week placebo-controlled trials in 156 patients aged five to 16 years of age. Outcomes demonstrated that children on risperidone achieved significantly improved scores for specific behavioral symptoms of autism compared to children on placebo. The most common side effects included drowsiness, constipation, fatigue and weight gain.

While efficacy has been demonstrated, concern remains about the misuse potential of risperidone and other antipsychotic drugs as a form of long-term chemical sedation, particularly with the most intellectually disabled children who may be the most likely to experience adverse drug effects. The overwhelming view, however, is that if antipsychotic drugs are used appropriately, they can have a positive role in the management of aggression associated with autism.

Complementary Approaches. In the absence of specific medical interventions for autism, parents and some healthcare professionals may choose complementary (i.e., alternative) therapies, such as art or music therapy; dietary restrictions including the elimination of gluten, sugar, chocolate, preservatives and food coloring; vitamin and mineral supplements; herbal remedies; or sensory integration, which focuses on reducing a child's hypersensitivity to touch or sound. Almost one-third of autistic children regularly receive a complementary therapy. Various surveys indicate that only 36 to 62 percent of caregivers who treated their autistic children with complementary therapies had informed the child's primary care physician.

Parents and caregivers should be encouraged to seek additional information when they encounter claims such as:

- treatments based on overly simplified scientific theories, and those supported primarily by case reports or anecdotal data rather than carefully designed studies;
- therapies claimed to be effective for multiple different, unrelated conditions or symptoms;
- claims that children will respond dramatically and some will be cured; and
- treatments that are said to have no potential or reported adverse effects.

Early Treatment. Individuals with autism won't outgrow it, but they can learn to function within the confines of the disorder, especially if treatment begins early. Early intervention is defined as treatment provided to children from birth to age three years. Research has clearly shown that early treatment, which consists of intensive, individualized behavioral interventions, can have a dramatic impact on reducing the symptoms of autism. Sadly, it is estimated that only 50 percent of autistic children are diagnosed before kindergarten.

Summary and Conclusions

Autism is a lifelong neurobiologic disorder that adversely affects quality of life. Early diagnosis of autism is often elusive. Its imprint on afflicted young people is so unique that the course of the disorder is difficult to predict in individual patients. In view of anticipated patterns of earlier identification and more proactive treatment of autism in years to come, the burden of autism on the health care system will continue to increase.

The content of this lesson was developed by the Ohio Pharmacists Foundation, UPN: 129-000-08-007-H01-P. Participants should not seek credit for duplicate content.

Continuing Education Quiz

This month's questions are taken from the article on "Autism and Its Treatment: A Primer for Pharmacists". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230-1701. There is no charge for this quiz for MPhA members (non-members $10.00). The completed quiz for this issue must be received by 7/15/2011. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly.
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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

1. In the U.S., autism affects an estimated one in:
a. 150 births. c. 15,000 births.
b. 1,500 births. d. 150,000 births.

2. The term *autism* has been defined as all of the following symptom patterns EXCEPT:
a. abnormal development of social reciprocity.
b. failure to use language for communication.
c. desire for sameness.
d. inability to perform mathematical tasks.

3. According to the table listing *Major characteristics of pervasive developmental disorders*, autistic disorder has an onset of:
a. <12 months of age.
b. <24 months of age.
c. <36 months of age.
d. <48 months of age.

4. The U.S. Institute of Medicine has stated that:
a. there is a link between thimerosal and autism.
b. there is no link between thimerosal and autism.

5. It has been reported that approximately three-fourths of patients with autism may be:
a. intellectually gifted.
b. mentally retarded.

6. By the time they reach adulthood, about one-third of children with autism develop:
a. schizophrenia.
b. hallucinations.
c. epilepsy.
d. delusions.

7. All of the following are included in the core group of behaviors physicians use to diagnose autism EXCEPT:
a. difficulty feeding and dressing oneself.
b inability to sustain conversation with others.
c. preoccupation with a particular object.
d. rigid adherence to established routines.

8. Girls with some autistic symptoms who also exhibit social withdrawal, regressed language skills, and hand wringing are most likely suffering from:
a. Asperger's disorder.
b. childhood disintegrative disorder.
c. pervasive developmental disorder not otherwise specified.
d. Rett syndrome.

9. The most common therapeutic agents employed to treat autism are the:
a. neuroleptics.
b. anticonvulsants.
c. stimulants.
d. antidepressants.

10. Common characteristics of persons with autism include all of the following EXCEPT:
a. avoiding eye contact.
b. begging to be held or cuddled.
c. having trouble adapting to a changing routine.
d. repeating actions over and over.


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MPhA

Maryland Pharmacist

VOLUME 86 NO. 3

President's Message
I Challenge You

Continuing Education
Access to Good Quality Dietary Supplements

Carol Stevenson, Pharm.D.
President

MARYLAND PHARMACISTS ASSOCIATION JULY/AUG/SEPT 2010

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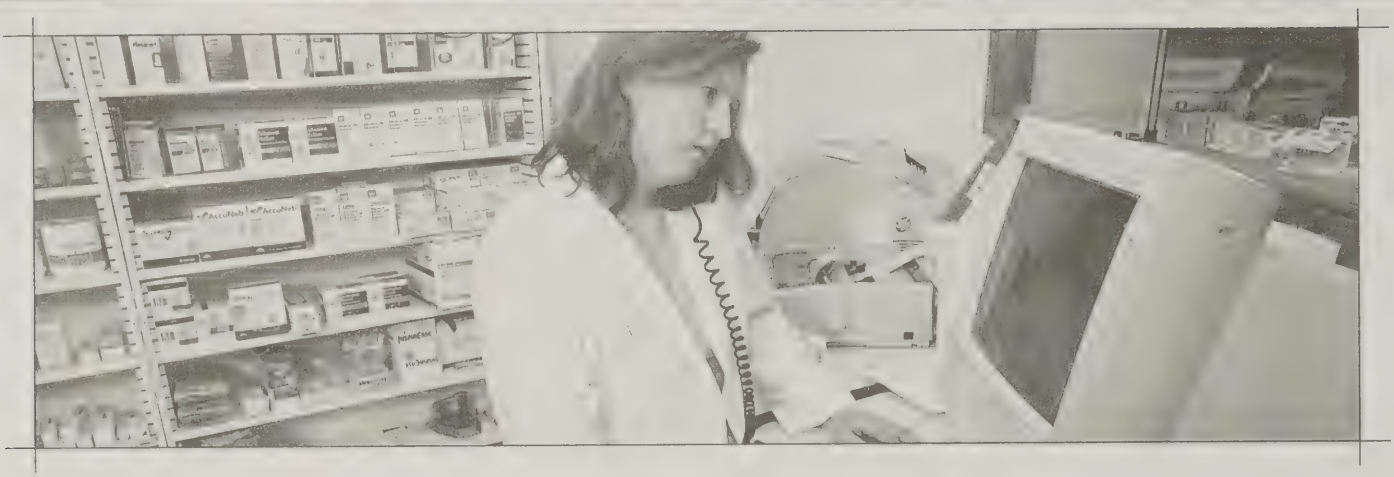

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President's Message

I Challenge You…

Carol Stevenson, Pharm.D.
President

As I look forward to our next year at Maryland Pharmacists Association, I have been thinking a bit about the past. My grandfather opened a pharmacy in 1910 on the plains of Oklahoma. What high hopes he had for the future, to practice pharmacy in a bustling new community and state. One hundred years later, the wind blows through his pharmacy in an abandoned building in a western ghost town. I am sure that he could not even imagine pharmacy today. Some of us began to practice in a world of manual typewriters, paper patient charts in hospitals, glass IV bottles, and manual insurance claims. These too are things of the past. Today we practice using tools I really never imagined when I began to practice: e-scripts, on-line charts, instant adjudication of claims, internet access to drug information, and on and on!

Pharmacy today is so much more than it was in the past and much more than the tools we use to provide pharmaceutical care. We are counseling patients, participating in MTM, P3, reviewing charts, making drug therapy decisions, providing immunizations, along with providing medications in a way that makes a real difference in the health of our community. I really believe that at long last our expertise is truly recognized, not just by our patients, but also by the medical community and the nation as a whole.

Our schools of pharmacy are producing new pharmacists who are well suited to meet the demands of the 21st century needs of patients and care givers. They are also bringing the rest of us practicing pharmacists the educational opportunities to make sure we can stay abreast with the exponentially expanding practice of pharmacy.

As a nation, we are struggling to provide healthcare for all citizens with new expansive legislation. The winds of change blow through healthcare and through the practice of pharmacy. My grandfather's pharmacy looks bit forlorn today, but the practice of pharmacy and the vision for the future looks bright with opportunity. We are not just pharmacists. We are specialists who provide all kinds of care to all kinds of patients. I believe that we will find our way in specialty practices, residencies, and in finding niche practices that will expand our opportunities. We also need to be good advocates for our profession as governmental agencies look at ways to provide healthcare for our country.

I challenge you, as pharmacists, to the vision for our organization: to promote excellence in pharmacy practice, strengthen the profession and advocate for all Maryland pharmacists. We need to support each other, to collaborate, to reach out to all pharmacists in our community and to advocate on a state and national level. We have a great heritage and a sense of history here in Maryland, but without a vision for tomorrow, pharmacy and MPhA could end up like my grandfather's drug store. I will work hard to support a bright vision of our future. I ask you to join in that endeavor.

The Evolution of Digitalis as a Cardiovascular Drug

by David Macharia, Pharm.D. Candidate

Since its discovery a few centuries ago, *digitalis* has come to play an important clinical role in the treatment of congestive heart failure (CHF) and chronic atrial fibrillation. It is the most common cardiac glycoside used in the clinical setting in the treatment of CHF and atrial fibrillation. It is extracted from the *digitalis lanata* species foxglove plant.

Digitalis exerts the following physiological effects when administered: it strengthens myocardium contraction, slows heart rate, and helps eliminate fluid from body tissues via urine – thereby lowering blood volume and decreasing the load on the heart. Due to its narrow therapeutic range and high potential for severe side-effects, its use is slowly falling out of favor.

To understand how digoxin came to be used in the clinical setting, we have to take a trip back to the discovery of *digitalis*. The folk use of *digitalis* dates back to more than 600 years ago. But it is only within the last 100 years that its therapeutic benefits have been clearly delineated and used in the clinical setting.

Digitalis is found in several species of the foxglove plant. Its development from herb to drug is instructive in exploring how standardization of some herbal products may afford increased benefits to patients. There are a multitude of herbal products in the market that propose to offer some health benefit. Standardization and isolation of the active substance(s) in herbal products – thought to provide some beneficial effects to patients – is a crucial step in being able to perform studies that may potentially lead to a drug by demonstrating safety and efficacy.

William Withering's effort to purify and standardize an assay containing the active ingredient *digitalis* over 200 years ago makes his discovery of the digitalis, the active ingredient in the fox glove plant, all the more impressive.

In his book titled "*Historical Medical Classics Involving New Drugs*," John C. Krantz offers a historical account of how William Withering transformed *digitalis* from folk-lore to a modern drug and how he came to be intricately associated with the history of *digitalis*.

William Withering was a man of versatile professions. In addition to being a physician, he was also a botanist and mineralogist. When he was queried as to what he thought was the active ingredient in the herbal concoction that an old woman at Shorpshire made, he was able to declare that the purple foxglove (*digitalis purpurea*) was the active herbal ingredient in the 20 herb preparation; the perceptive botanist that he was. Being a biennial plant, Withering believed that the foxglove was more likely to have a consistent level of the active ingredient in the herbal preparation[1]. He verified this idea by isolating and simplifying the 20 herb preparation – whose secret formula was guarded by the old woman of Shropshire in 1785.

Purple Foxglove
(Digitalis Purpurea)

The formulations that he made of *digitalis* were decoction, infusion and later a powder. He seldomly used *digitalis* in his medical practice and prescribed it only as a last resort when other treatments were unsuccessful. In his use of *digitalis*, he says that the cases that he used *digitalis* for were those that may "… truly be considered as cases lost to the common run of practice, and only snatched from destruction by the efficacy of the digitalis."[3] He considered *digitalis' main action to be in diuresis*, but was keenly aware that it had some effect on the actions of the heart. He left it up to time to determine if he "…imposed

upon himself and others, or contributed to the benefit of science and mankind"[3] by discovering *digitalis*. His view on *digitalis*' main action persisted in the medical community for more than a century[1].

In the early 1900's the cardiac effects of *digitalis* came to be recognized. Its cardiac action was studied and described by Sir Mackensie and Arthur Cushny in 1911. The experiment that they conducted was instrumental in describing *digitalis*' effects on the heart. The experiment involved injecting *digitalis* into the beating heart of an open-chested dog and observing the effects that resulted[2].

In the 1920's, *Digitalis Ianata* was found to have greater physiological potency than *Digitalis purpurea* when it was used as a powder. In an attempt to isolate the glycosides in *Digitalis Ianata*, Sydney Smith discovered a cardiac glycoside that he named *digoxin*. In time, *digoxin* came to be used more often than *Digitalis purpurea* due to its favorable pharmacokinetics. For instance, it did not bind to plasma and tissue protein as strongly as *digitoxin* (cardiac glycoside obtained from *Digitalis purpurea*), hence its therapeutic benefit was realized sooner. In addition, by not accumulating in the body, it was cleared from the body faster thereby reducing severe side-effects associated with cardiac glycosides.

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Therapeutically Speaking...

Don't go it alone: Support staff and student pharmacists can help with your immunizations program

By: Cherokee Layson-Wolf, PharmD and Khiana Willis, PharmD

So you've started giving immunizations—congratulations, but do you ever feel like a one-man or one-woman show? This doesn't have to be the case—you don't have to do it all by yourself! While only a licensed pharmacist may give immunizations, give some thought to using your pharmacy support staff such as pharmacy technicians, clerks and student pharmacists to help grow your immunization practice. Pharmacists are often pulled in multiple directions and may find it difficult to manage an immunization program on their own. Pharmacy support staff and student pharmacists in both introductory and advanced pharmacy practice experiential rotations can be a great complement to your immunizations services. Empowering these members of your pharmacy will offer significant support, allowing you to grow your immunization practice. This article will provide some tips on how to utilize support staff and student pharmacists in your immunization program.

Student Pharmacists on Introductory Pharmacy Practice Experience (IPPE) and Advanced Pharmacy Practice Experience (APPE) experiential rotations:

- *Protocol development and revision*: Flu immunization protocols have to be updated on a yearly basis, and updates should be done before you revisit your protocol physician. Have your student pharmacist review your existing protocol and evaluate whether any updates need to be made. You can discuss any recommendations with your student pharmacist and make any appropriate revisions. This will help the student pharmacist learn about the components of an immunization protocol, and also help you keep your protocol up to date.

- *Developing immunization educational materials for your pharmacy*: Have your student pharmacist develop a flyer or pamphlet educating your patients about particular immunizations they might be a good candidate for.

- *Checking on updated vaccine information statements (VIS)*: Vaccine information statements suck as that for influenza are updated once a year, and others are updated on a regular basis. It is required that you provide the most recent version of the VIS when you are immunizing. In addition, you may have patients for whom English is not their first language, or they may be non-English speaking. Have your student pharmacist determine which languages may be prevalent at your pharmacy and find VIS' that you can use in your pharmacy so you will be able to immunize patients who may not speak English.

- *Marketing pieces*: In addition to word of mouth marketing, in store advertising is likely all you need to market your immunization services. Your student pharmacist could create flyers advertising which immunizations you provide. These flyers can be posted in the pharmacy or handed out with each prescription. In addition, your student pharmacist can help develop marketing pieces for providers, such as informational faxes you can send to physicians to market your immunization services.

- *Advocacy*: Since students on experiential rotations are required to interact with patients, they can take this opportunity to identify patients who are candidates for specific immunizations and make these recommendations to your patients under your supervision. They can encourage your patients to discuss recommended immunizations with their physician and to receive appropriate vaccinations at your pharmacy.

- *Immunization administration for trained student pharmacists*: Per the Maryland regulations, student pharmacists can immunize

if they: 1) have completed a board approved training program, 2) have active CPR training, 3) are in an experiential learning program, and 4) are supervised by a pharmacist preceptor who is also registered with the Board of Pharmacy to immunize. When a student pharmacist immunizes a patient at your practice, they are required to include their name and credentials (e.g. Name, Student Pharmacist) when documenting the immunization and their pharmacy preceptor must also include their name and credentials and signature.

- *Addressing questions about immunizations*: When a patient comes to the pharmacy asking questions about vaccinations, your student pharmacist can help address these questions. This will help develop their drug information skills, their knowledge base, and let them sharpen their skills.

- *Updating pharmacy staff on new immunization information*: Drug information is constantly being updated, and immunizations are no exception. Your student pharmacists can provide you and your staff with relevant immunization updates to make you aware of any new immunizations, updated immunization recommendations, or other important issues such as vaccine management. Unfortunately, this will not help you meet your immunization continuing education requirements but will help you keep abreast of new developments.

Support staff:

- *Maintaining supplies*: Since many of your staff members are likely already involved in maintaining your physical inventory, it is an easy transition to delegate the maintenance of immunization supplies to your support staff. Ensuring that you are adequately stocked with supplies to perform immunizations especially during peak immunization times can be invaluable. Items such as syringes, alcohol swabs, and cotton balls to name a few should remain plentiful during these times. Creating an immunization supply list (a good one is available on the Immunization Action Coalition website - www.immunize.org) can help make this task easier to manage.

- *Monitoring vaccine storage temperature*: Proper storage of the vaccine is an important part of immunization services. As with other pharmaceutical products that may require refrigeration, this is most likely a task already being performed by your staff. Pay close attention to storage requirements for a particular vaccine. Determine whether the product requires refrigeration (e.g. the flu vaccine) or freezer storage (e.g. herpes zoster vaccine). Proper storage ensures that our patients are receiving proper care. Assign a particular pharmacy technician or pharmacy clerk the task of recording refrigerator and freezer temperatures where you store your vaccines.

- *Marketing your immunization program*: Marketing is a very large part of growing your immunization practice. Making sure that your patients are aware of what you have to offer in a clear and concise manner ensures that they not only know what you have to offer, but if done properly will prompt your customers to inquire about what you can do for them. Marketing can be done in various forms and a little creativity can go a long way. Examples may include flyer distribution within bags or posted visibly within the store for the patients, targeting area physicians to make them aware of your services, utilizing your phone system to advertise your services, targeting groups with an unmet need with whom you are able to meet (e.g. diabetics, patients > 60 years of age), or utilizing glass doors and windows to design a fun visual that also becomes a show stopper as your patients walk through the door. Instruct your staff to refer patients to you so that you can use your face to face counseling time with patients to better explain your immunization services. You may even consider instituting a competition between your technicians, and provide an incentive for the technician or clerk who recruits the most number of patients or customers to receive the flu vaccine. As the flu season gets underway, patients are constantly inquiring about cough and cold items at your front counter, this is your staff's opportunity to shine!

- *Processing customer's paperwork*: Your front staff is your first line of defense to taking the load off when processing your patients. Ensure that your staff is properly trained on the appropriate forms required by your pharmacy and any other forms required to comply with state regulations. These documents may include the vaccine information sheets, consent forms, vaccination screening forms, or obtaining insurance or payment information.

- *Scheduling appointments*: Developing a system of scheduling appointments can eliminate confusion and wasted time, making it a painless process for you, your staff, and your patients. There are various ways to keep track of your scheduling. If your pharmacy does not have a sophisticated computer system, a simple day planner would get the job done. This calendar may be used to designate a specific block of time for immunizations which may vary daily based upon your workload. Make sure that you give yourself a realistic timeframe for scheduling (e.g. one appointment per hour). You may also choose to work immunizations into your workflow as a prescription so that it demands your attention in the order of priority so that time spent is equitable amongst your patients. Computer calendar programs such as Outlook or creating calendar templates in Microsoft Word may also help you to stay on track. Educate your staff on providing the patients with a realistic timeframe for the completion of their immunization.

- *Billing*: Payment issues are commonly a source of confusion not only for the patient but also your staff. Your support staff is frequently used to process payments for other goods and services. Preparing a reference sheet of procedures for billing of the vaccine product and administration fee, if applicable, can help your staff become experts in no time. Ensuring that your staff is knowledgeable about billing requirements for commonly seen plans will make for a seamless experience in the eyes of your patient.

As you can see from these suggestions, there are many opportunities for your support staff and student pharmacists to help establish, maintain and grow your immunization program. Share this article with your pharmacy support staff or student pharmacists on rotation to give them ideas of how to contribute as well. Taking the time to plan this out can be highly instrumental in making your immunization program even more successful!

Edited by:
Dr. Mary Lynn McPherson
Professor, University of Maryland School of Pharmacy

Introducing "*Medication Therapy Management (MTM) Light*" Series: Practical Guidance for Maryland Pharmacists to Develop and Implement MTM Services

Hoai-An Truong, PharmD, MPH and Kristen Fink, PharmD, CDE

Whether practicing in an ambulatory clinic, community, consulting, health-system, or specialized setting, pharmacists have the challenges and opportunities in providing medication therapy management (MTM) services to optimize patient care and advance the pharmacy profession. Realizing that MTM is the current trend with exciting potentials in pharmacy practice and health care landscape to improve patient care, pharmacists have asked the questions: "*How can I obtain training to develop and implement MTM services? How can I reach out and educate patients and providers about MTM? Where can I find resources and supports for providing MTM services?*"

Over the last several years, the MPhA Professional Development Committee has worked to address Maryland pharmacists' needs through a variety of strategies: (1) collaboration with the Maryland Chapter of American Society of Consultant Pharmacists (MD-ASCP) and University of Maryland School of Pharmacy (UMSOP) to implement the "Maryland MTM Training Initiative for Pharmacists/Preceptors" utilizing the American Pharmacists Association and American Society of Consultant Pharmacists (APhA-ASCP) national MTM certificate training program, (2) publication of two articles on MTM opportunities and resources for pharmacists in the *Maryland Pharmacist*, (3) and development of posters for the 2010 Annual Maryland Pharmacy Legislative Day to educate legislators and the public about MTM and role of the pharmacist in public health. These posters are kept at the MPhA Headquarters and available for pharmacists' use as needed. The goals of the committee are to:

- Provide opportunities, resources and training for pharmacist's continuing professional development
- Increase awareness of MTM services among pharmacists in Maryland and make MTM a practical concept to be incorporated into the daily practice of pharmacists
- Identify opportunities for pharmacists to provide cognitive services and receive compensation
- Meet expectations set by MPhA 2010 Strategic Plan

The "Maryland MTM Training Initiative for Pharmacists/Preceptors" launched in early 2008 has trained 230 pharmacists and student pharmacists through 9 programs to date, with the 10th session scheduled for October 9th, 2010. Recently, a survey of MTM trained participants was developed and administered to assess needs and interests for MTM resources and support network and next level MTM program workshop. Results will be published when available.

Regarding the two publications in *Maryland Pharmacist*, the first article provided a review of the MTM core elements, perceptions, and opportunities for pharmacists; the second article focused on national and Maryland initiatives and resources.[1,2] Various practical resources, tools and websites are available for pharmacists to develop and implement MTM services.

In a continued effort to meet Maryland pharmacists' needs, the Professional Development Committee will launch a "*Medication Therapy Management (MTM) Light*" Series: Practical Guidance for Maryland Pharmacists to Develop and Implement MTM Services as proposed by current MPhA Board of Trustees Chairman Butch Henderson, PD, past-president of MPhA 2009-2010 to assist pharmacists incorporating MTM services into current pharmacy practice. With this introduction, there will be a series of journal article highlighting a variety of topics, including: (1) collaborating with physicians; pharmacist-physician relationships, (2) conducting a SWOT analysis; obtaining pharmacist's credentials and National Provider Identification (NPI) for clinical

services, (3) documenting, monitoring and tracking patient care, and (4) obtaining compensation/reimbursement for clinical/cognitive services. Look for these articles in future issues of the journal.

For questions regarding MTM opportunities or suggestions, please contact MPhA Professional Development Committee Co-chairs Kristen M. Fink, PharmD, CDE, Clinical Pharmacy Specialist, Kaiser Permanente and Fink's Pharmacy at fink462@hotmail.com or Hoai-An Truong, PharmD, MPH, Assistant Director of Experiential Learning at University of Maryland School of Pharmacy, and MTM Pharmacist at Mercy Health Clinic, Primary Care Coalition of Montgomery County, at htruong@rx.umaryland.edu.

Previous articles on MTM in *Maryland Pharmacist*:

1. Fink KM, Truong HA, Malone K. Medication therapy management: a review of the core elements, perceptions, and opportunities for pharmacists. *Maryland Pharmacist*. 2008; 84(3):22-3

2. Truong HA, Lodowski KL, Shaw JE, Fink KM. Medication therapy management: opportunities and resources for pharmacists. *Maryland Pharmacist*. 2009; 85(1):13-4.)

Continuing Education
Access to Good Quality Dietary Supplements

This continuing education monograph is adapted from the United States Pharmacopeial Convention (USP) series of white papers prepared by the Council of the Convention (CoC) titled "Focus On: Future Directions for USP." The learning objectives and assessment questions were developed by National Alliance of State Pharmacy Association's (NASPA) Continuing Education Advisory Panel. No financial support was received for this activity. This activity may appear in other state pharmacy association journals.

Council of the Convention Section on the Quality of Food Ingredients and Dietary Supplements, Mary H. Hager, Ph.D., R.D., F.A.D.A., Section Chair (American Dietetic Association), E. James Bradford, Ph.D. (AOAC-International), Marvin M. Lipman, M.D. (Member-at-Large), Lyn O. Nabors (International Food Additives Council)

Goals:
The goals of this lesson are to provide background information on dietary supplements and to review proposals for consideration to further improve the quality of dietary supplements.

Objectives:
At the conclusion of this lesson, successful participants should be able to: 1. Describe the regulatory framework of dietary supplements. 2. Give examples of the proposals that could be considered to further improve the quality of dietary supplements.

INTRODUCTION

The 1994 Dietary Supplement Health and Education Act (DSHEA) amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) provided a regulatory framework to allow marketing of vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Now, more than 15 years later, a vast array of dietary supplements in different combinations and amounts are available to United States patients/consumers. Sales of dietary supplements are approaching $25 billion/year, with about $4 billion of this amount representing sales of botanicals. While DSHEA was instrumental in providing consumers with easy access to dietary supplements, a recent U.S. Government Accountability Office (GAO) report stated that consumers of dietary supplements are not adequately protected under current

U.S. law and regulations.[1] Pre-market oversight and registration of products are recommended in the GAO report.[2] Outside the United States, dietary supplements are frequently considered as traditional medicines with few standards and conformity assessments to these standards. In this white paper, USP's Council of the Convention Section on the Quality of Food Ingredients and Dietary Supplements provides background information on the topic and advances proposals for consideration by the Convention membership to further improve the quality of dietary supplements.

National Approaches

1. Congress: Provisions of DSHEA

Through DSHEA, Congress defined dietary supplements as "foods." As with all foods, DSHEA provisions in the FDCA do not require pre-market review of a dietary supplement by the Food and Drug Administration (FDA) if the ingredients have a safe history of use in food or supplements prior to 1994. Instead, Congress put in place a notification process for a new dietary ingredient to ensure that ingredients that do not have a safe history of use are reviewed by the FDA prior to entry into the U.S. market. In addition, DSHEA essentially places the burden of proof on the FDA to demonstrate that a dietary supplement presents "significant or unreasonable risk of illness or injury" before it can be removed from the market.

With regard to the United States Pharmacopeia (USP), Section 403(s)(2)(D) of the FDCA states that if a dietary supplement is 1) covered by the specifications (tests, procedures, and acceptance

[1] Government Accountability Office report. 2009 Dietary supplements. FDA Should Take Further Actions to Improve Oversight and Consumer Understanding http://www.gao.gov/new.items/d09250.pdf.
[2] Ibid.

criteria of a monograph) of an official compendium of the United States (USP, National Formulary [NF], or the Homeopathic Pharmacopoeia), 2) is represented as conforming to the specifications of an official compendium, and 3) fails to so conform, then the supplement is considered to be misbranded. Accordingly, unlike the provisions relating to prescription drugs (where conformance with USP standards is mandatory, whether labeled as such or not), Section 403(s)(2)(D) of the FDCA makes compliance with the specifications of an official compendium strictly voluntary for dietary supplement manufacturers (unless the manufacturer chooses to represent the product as conforming to USP). As a consequence, this statutory reference to official compendia provides legal recognition to USP, but effectively creates a disincentive for its use, because it exposes only those manufacturers who so label (and not others who make no reference to USP standards at all) to a potential misbranding violation if found not to conform to USP.[3]

2. The Food and Drug Administration

In 2007, the FDA finalized Current Good Manufacturing Practices (cGMPs) for dietary supplements. These regulations allow manufacturers to establish product specifications and to use "appropriate and scientifically valid" methods to determine whether those specifications are met. The cGMPs do not define the words "scientifically valid" nor is validation of analytical procedures required. The FDA has indicated that "a scientifically valid method is one that is accurate, precise, and specific for its intended purpose—in other words, a scientifically valid test is one that consistently does what it is intended to do. As a result, dietary supplement manufacturers develop private procedures, tests, and assays, which may or may not receive regulatory scrutiny. Standards for a dietary supplement under a specified name may not have comparable requirements and thus may be dissimilar in quality, benefit, and safety to consumers. The cGMPs do not require dissolution and disintegration testing, and manufacturers set their own limits for contaminants such as heavy metals, microbial limits, fungal toxins, or pesticides. USP has published an article describing the current regulatory scheme as one that creates "standards without standardization."[4]

3. United States Pharmacopeial Convention

Following enactment of DSHEA in 1994, the 1995 USP Convention adopted Resolution 12 that encouraged the USP to explore the feasibility and advisability of establishing standards and developing information concerning dietary supplements. This resolution was taken up and implemented by USP's Board of Trustees and Council of Experts, resulting in a well-evolved section of USP for dietary supplement monographs, with allied USP Reference Standards offered in USP's catalogue.[5] USP32-NF27 now contains approximately 430 dietary supplement and ingredient monographs and general chapters, which cover a large percentage (+90%) of the dietary supplements commonly marketed in the United States. USP's Council of Experts Dietary Supplement Information Expert Committee applies admission criteria together with a safety review guideline to allow exclusion of some dietary supplements from USP, even though they may be legally marketed in the United States. This approach mirrors the work of the Scope Committee of the Committee of Revision (the predecessor of the Council of Experts) that ended in the 1990s. USP also includes a General Chapter on Manufacturing Practices for Dietary Supplements <2750>, which was developed prior to finalization of FDA's cGMPs and is generally more stringent and specific than those regulations. In June 2009, USP introduced a separate USP Dietary Supplements Compendium that includes official text from USP (monographs and general chapters relating to dietary supplements) as well as authorized explanatory text and graphics intended to provide useful information to dietary supplement manufacturers.

International Approaches

While vitamins, minerals, amino acids, botanicals, and other plant and animal substances are available in the U.S. as dietary supplements, they are variably

[3] It should be noted that the FDA has indicated that DSHEA will not apply to dietary supplement products intended for use in animals. As such, animal dietary supplements currently are regulated generally as "food" without the additional protection afforded human dietary supplement products under DSHEA. It is generally felt in the veterinary community that the need for evidence of quality, safety, and efficacy are similar for veterinary and human patients alike. For more information, see *Safety of Dietary Supplements for Horses, Dogs and Cats*, Committee on Examining the Safety of Dietary Supplements for Horses, Dogs and Cats, National Research Council, National Academic Press, 2008.

[4] Miller RK, Celestino C, Giancaspro GI, Williams RL. 2008. FDA's dietary supplement CGMPs: Standards without standardization. *Food and Drug Law Journal* 63 (4), 929-942+iv.

[5] More information on USP dietary supplements Expert Committees is available through http://www.usp.org/support/products/uspNewslettersRequest.html

regulated as health products, traditional medicines, or drugs in other countries. This varied international approach on the regulation of dietary supplements provides different paradigms for consideration and exploring options for domestic regulatory oversight. Quality standards also are quite variable around the globe. Issues of quality are present in the international commerce of dietary supplements, which is evident in cases such as protein adulteration with melamine or dietary supplements containing toxic metals, high levels of pesticides or unapproved drugs. Information from the World Health Organization (WHO) details the widespread consumer misconception that "natural" always means "safe," and a common belief that remedies from natural origin are harmless and carry no risk. Also of concern is that healthcare providers are frequently unaware of the dietary supplements their patients are taking; either because they do not ask, or patients do not offer the information. Under the current law and regulations, there is no way of knowing the quality standards to which each product is held, and thus, there is no way to determine whether two products with the same dietary supplement ingredients are the same or different.

Proposals

The Council of the Convention Section on Food Ingredients and Dietary Supplements suggests for consideration the following opportunities for possible USP Convention action and improvement in the regulation of dietary supplements.

1. Public Monographs and Reference Materials

The universe of products in the market is constantly expanding, creating gaps where monographs and reference materials are missing. To the extent feasible, documentary standards and reference materials offered by USP should expand to cover all the products in the dietary supplements market.

2. Adherence to Public Standards

Public quality standards arising from the open and participatory process conducted by USP conserve both regulatory and manufacturer resources. They work to achieve consistency in the quality of a dietary supplement both within and between manufacturers, and allow updating. This consistency is more likely to be achieved if manufacturers are required to comply with public standards. Thus, USP might consider informing and engaging in discussions with Congress about the desirability of strengthening section 403(s)(2)(D) of the FDCA to require dietary supplements and dietary supplement ingredients to conform to the standards established in USP-NF, where such standards exist. USP also might consider making Congress aware of the benefits of strengthening the adulteration provisions of the FDCA to ensure that all dietary supplements conform to the relevant standards promulgated in USP-NF. However, it is not clear, at this time, that industry supports such mandatory standards

3. International Harmonization

Amidst the increasingly complex global supply of dietary supplement ingredients and products, ensuring quality and harmonization of standards is important, irrespective of how dietary supplement products are labeled and regulated—whether as traditional medicines, drugs, or supplements. Global harmonization of public standards would ensure quality, identity, and label uniformity in international commerce, and could facilitate international commerce of good quality dietary supplements. To start its work in this area, USP standards and analytical methods could complement the descriptions of quality, dosage, safety, and pharmacological activity of botanical monographs offered by other standards setting bodies of the world. For these reasons, USP should cooperate with international health organizations to promote standards for traditional medicines that are also dietary supplements in the United States. Examples of such organizations include the WHO, the Canadian Natural Health Products Directorate in Health Canada, the European Directorate for the Quality of Medicines and HealthCare (EDQM), and the Indian and Chinese Pharmacopoeia Commissions.

4. Education

There is a dearth of unbiased dietary supplement information for consumers and practitioners. Gaps in practitioner training and consumer education are clear impediments to the safe use of dietary supplements. Practitioners should receive training on proper counseling of consumers on the use of dietary supplements and consumers should be educated about the importance of disclosing such usage to healthcare providers. In this way, practitioners and consumers can monitor and prevent possible adverse effects that

may occur from the combined use of certain dietary supplements and drugs.

USP could expand its educational programs to meet the needs of practitioners and patients/consumers with respect to dietary supplements. The USP Dietary Supplements Information Expert Committee earlier recommended education of practitioners regarding suitable practices for safe use and prevention of interactions with other therapeutic agents. USP should consider developing Pharmacopeial Education courses for practitioners and consumers in this regard, and additional courses on compendial approaches to quality standards for dietary supplements to help manufacturers, testing labs, and regulators understand the value of USP public standards and reference materials.

5. Verification

USP Verification Programs could also be used to increase confidence that ingredients and products moving in the international market comply with the quality specifications to help ensure public safety, including absence of known/identified adulterants and contaminants. Although FDA has not endorsed the use of third party certifications of dietary supplements, it has recognized the value of third-party certifications in its recent guidance on foods. Broad implementation of USP's Verification Programs for dietary supplements and dietary supplement ingredients could assist in raising supplement quality, help patients make informed decisions, restore consumer confidence, and allow healthcare practitioners to recommend verified dietary supplements with some level of confidence. The various elements of USP's Verification Programs (audits, testing, document review, and market surveillance) would act synergistically with the cGMPs already in place, thus helping conserve FDA resources. Because cGMPs provide minimum requirements, implementation of USP Verification Programs would add value for greater assurance of the quality of supplements.

The concern about the quality and purity of ingredients moving in the international market also could be addressed through a system of USP Verification Programs' inspecting companies and testing products overseas. With sites in China, India, and Brazil, USP is very well positioned to contribute worldwide to raising the quality of dietary supplements. It is also possible that the challenges faced by regulatory differences with other countries could be addressed through credible USP Verification Programs.

6. Regulatory Oversight

Dietary supplement product registration or pre-market notification might be considered as a means of monitoring the number and type of dietary supplements moving in commerce in the U.S. and helping to assure the safety of dietary supplements prior to sale to the consumer. To accomplish this, the FDA would need sufficient resources to adequately assess and address the safety of dietary supplement products, and the FDCA would need to be amended to provide the FDA with authority in this area.

The Council of the Convention Section on Food Ingredients and Dietary Supplements welcomes input on these proposals from the Convention, as well as additional comments on how USP might build upon its past efforts and expand its work to help assure the quality and appropriate use of dietary supplements worldwide.

ABOUT USP and NASPA

The United States Pharmacopeia (USP) is an official public standards–setting authority for all prescription and over–the–counter medicines and other health care products manufactured or sold in the United States. USP also sets widely recognized standards for food ingredients and dietary supplements. USP sets standards for the quality, purity, strength, and consistency of these products–critical to the public health. USP's standards are recognized and used in more than 130 countries around the globe. These standards have helped to ensure public health throughout the world for close to 200 years. More information can be found at www.USP.org

The National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among state pharmacy associations and pharmacy leaders nationwide, and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives (NCSPAE). More information can be found at www.naspa.us

WHO. 2004. Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance systems. WHO Department of Essential Drugs and Medicines Policy: Geneva. http://apps.who.int/medicinedocs/index/assoc/s7148e/s7148e.pdf

Gardiner P, Sarma DN, Low Dog T, Barrett ML, Chavez ML, Ko R, Mahady GB, Marles RJ, Pellicore LS, and Giancaspro GI. 2008. The state of dietary supplement adverse event reporting in the United States. Pharmacoepidemiology and Drug Safety. 17: 962–970.

Ko RJ. 2004. A U.S. perspective on the adverse reactions from traditional Chinese medicines. J Chin Med Assoc. 67(3):109-116.

Gardiner et al, 2008 (see reference 5 above).

Third-party verification – The FDA is endorsing third party verification of foods through its Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds. 2009. http://www.fda.gov/RegulatoryInformation/ Guidances/ucm125431.htm

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Best Prescription for Pharmacy Theft is Prevention and Preparation

Pharmacy robberies and burglaries are a growing concern nationwide. Prevention and preparation are the two best methods to keep pharmacy staff and customers safe from pharmacy robberies and prevent burglaries. There are several actions pharmacists can take immediately to reduce risks and help law enforcement solve crimes if they do occur.

Make your pharmacy a less desirable target for robberies or burglaries:

- Contact your local law enforcement to ask for a security assessment of your pharmacy, and for recommendations for deterring would-be criminals.
- Ensure that the parking lot and all entrances and exits are well lit.
- Install shatterproof front doors and windows or make windows otherwise inaccessible.
- Install electronic burglar alarm systems with loud alarms and flashing lights.
- 90% of robbery suspects enter through the front door. Signs placed outside the entrance will inform potential thieves that the location is under electronic surveillance.
- A very visible, color camera aimed at the front entrance, along with other visible cameras and monitors are great deterrents for would-be thieves.
- Do not stock controlled substances where customers can see them – lock them in a vault or safe.
- Develop written security procedures and train staff. Conduct regular trainings, updates and practice drills to help you and your employees be better prepared and able respond in the event of an actual crime.
- Always have at least two employees in the store.

- Pay close attention to suspicious activities and call police if you feel uncomfortable with a customer's behavior.
- Do not allow any non-pharmacy employee (i.e. telephone or heating repair technicians) to have access to the pharmacy area without verification.
- Train pharmacy staff to identify potentially forged prescriptions and verify any suspicious prescriptions with the prescriber.

Prepare for robberies – safety first, evidence second:

- Wipe down pharmacy counters at the beginning of each shift and at closing time to clear away existing fingerprints and make the surface a good place to recover evidence.
- Install hidden alarm/panic buttons.
- Practice being a good witness – robberies typically only last a few moments – teach staff to remain calm and look for descriptive details.

Train employees how to respond during a robbery:

- Stay calm
- Do not stare at the thief
- Do not attempt to confront or chase the thief
- If safe to do so, trigger silent alarm
- Make mental notes of descriptive details
- Give the thief what he/she is demanding

After a robbery has occurred:

- Secure the store – lock the front doors
- Make note of the get away vehicle if it doesn't put anyone at risk – get the make, color, license number of the vehicle
- Call police if they have not yet been notified
- Do not touch the counter or any other surface touched by the thief
- Ask witnesses to remain inside the store, but away from the crime scene
- Give witnesses pen and paper and ask each person to provide name, contact information and any details that might be helpful to police

To learn more about how you can protect your pharmacy, obtain training materials and become part of the RxPATROL® data reporting effort to help solve pharmacy crimes, visit www.rxpatrol.com. RxPATROL® is a national database that tracks, analyzes and provides information on pharmacy crime to law enforcement and pharmacies. Created in May 2003 with funding from Purdue Pharma L.P., information from RxPATROL® is helping law enforcement solve crimes while teaching pharmacy owners how to protect their businesses and customers.

Continuing Education Quiz

This month's questions are taken from the article on "*Access to Good Quality Dietary Supplements*". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230-1701. There is no charge for this quiz for MPhA members (non-members $ 10.00). Program release date: October 15, 2010. *Program expiration date: December 31, 2011.* This program provides for 1.00 contact hour ((0.1 CEU) of continuing education credit. A continuing education certificate will be sent to you within six to eight weeks. ACPE# 0144-9999-10-062-L01-P Please type or print clearly.

Name_____

Address_____

City, State, Zip_____

Daytime Phone_____

Date Completed _____

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

1. The Dietary Supplement Health and Education Act was introduced in what year?
   a. 1993
   b. 1994
   c. 1995
   d. 1996

2. Sales of botanicals are approximately ___ of an almost $25 billion/year business.
   a. 1 billion
   b. 2 billion
   c. 3 billion
   d. 4 billion

3. Through the Dietary Supplement Health and Education Act (DSHEA) Congress defined dietary supplements as which of the following?
   a. Drugs
   b. Vitamins
   c. Foods
   d. Botanicals

4. Which of the following is considered an official compendium of the United States
   a. Unites States Pharmacopeia
   b. National Formulary
   c. Homeopathic Pharmacopeia
   d. All of the above

5. In which year was the Current Good Manufacturing Practices (cGMPs) for dietary supplements finalized by the FDA?
   a. 2000
   b. 2003
   c. 2007
   d. 2009

6. Which of the following is false regarding cGMPs?
   a. They were finalized by the FDA
   b. They do not define the words "scientifically valid"
   c. They allow manufacturers to establish product specifications
   d. They require dissolution and disintegration testing

7. In what year did the USP Convention adopt a resolution that encouraged the USP to explore the feasibility and advisability of establishing standards and developing information concerning dietary supplements?
   a. 2005
   b. 1965
   c. 1995
   d. 1985

8. Which of the following includes official text from USP as well as authorized explanatory text and graphics intended to provide useful information to dietary supplement manufacturers?
   a. USP Dietary Supplements Compendium
   b. Manufacturing Practices for Dietary Supplements
   c. Homeopathic Pharmacopeia
   d. None of the above

9. Which of the following is available in the U.S. as a dietary supplement?
   a. Vitamins
   b. Minerals
   c. Amino acids
   d. All the above

10. Which of the following is true regarding public quality standards?
    a. They conserve only regulatory resources
    b. They work with only certain manufacturers
    c. They do not allow updating
    d. They arise from the open and participatory process conducted by USP

11. Global Harmonization would ensure
    a. Quality
    b. Identity
    c. A+B
    d. None of the above

12. USP does NOT have a site in which of the following countries?
    a. France
    b. China
    c. India
    d. Brazil

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President's Message

Visions…

Carol Stevenson, Pharm.D.
President

Crystal balls and magic wands… Wouldn't it be wonderful to look into the future, wave a magic wand make the profession of pharmacy to our liking, ala Harry Potter. Just when we think we have a vision of the future of healthcare and our place in it, change looms. Uncertainty and change in our lives, our finances, our communities, and our professions seem to be the new reality.

What can we do to ensure that our profession continues to thrive, and to provide the best care possible to our patients and the best services to our community? How can we ensure that student pharmacists arrive in our profession on the cusp and ready to meet the challenges we see now, and even those that we cannot yet imagine? How can those of us out working in the profession keep up with the demands of our daily work and the need to constantly update our knowledge? How can we make sure our voices are heard, not only in the healthcare arena but also in the community as a whole? How can we plan for the future in a changing profession so that we can use our knowledge and expertise more fully, benefiting our patients, our community and our colleagues?

I would like to think that our organization is helping to make the future happen! I think we were pretty smart to sit down last spring and have a strategic planning session. We made plans for the future of our organization. New ideas were floated, tasks were assigned, and committees organized around this new strategic plan. Not every idea will be successful or every task completed, but we can use our plan as a guide to the future.

We have had the privilege of holding board meetings at Notre Dame and University of Maryland at Baltimore schools of pharmacy this year. It has been amazing and heartening to see the enthusiasm for our profession and its future in both faculty and students. I have visited the UMES campus on the eastern shore, and had the opportunity to talk to the dean and some of the students there. They too share the enthusiasm!

Our meetings and conventions committee is working to bring first class educational programs to our members and reach out to other like-minded organizations. The professional development committee is providing training and working on an MTM summit! The legislative committee with MPC is working to make sure the legislature understands our commitment to both public health and our profession. Our executive director works every day to promote the profession and make sure our interests are protected. Other committees work to provide first class communications, financial stewardship, scholarship opportunities for students, membership growth, management and protection of our artifacts, and personnel management.

What are you doing? I know you are out there working hard every day, but what are you doing about the future? Alone, making meaningful changes can be pretty difficult, but together, we can make the future of pharmacy into the best possible. There is opportunity to serve your profession, your community and yourself by volunteering on an MPhA committee, giving of your time on Legislative Day in Annapolis, attending our Mid-year and Annual Convention, and coming to a board meeting to express your opinion! I invite you to become an active participant in your state professional organization. If you leave the future up to others, it might not be the future you were wishing for.

Recognizing Pharmacy Excellence
The 2011 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 1800 Washington Blvd., Suite 333, Baltimore, Maryland 21230-1701.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the Annual MPhA Convention.

For consideration, all nominations must be received no later than ***Thursday, March 31, 2011.***

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
  Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. ***Who is Eligible:*** Any MPhA pharmacist member who graduated from pharmacy school in 2001 or after.

- **Maryland Pharmacists Association Honorary President**
  An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time. ***Who is Eligible:*** Any long standing contributor to the profession or the Association.

- **MPhA Mentor Award**
  This award recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the Award.

- **Seidman Distinguished Achievement Award**
  Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

- **Pfizer Bowl of Hygeia Award**
  The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. ***Who is Eligible:*** Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

- **Innovative Practice Award**
  Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association
Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than ***Thursday, March 31, 2011***. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐ ***Pharmacist Mutual Distinguished Young Pharmacist Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Seidman Distinguished Achievement Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Innovative Practice Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***Pfizer Bowl of Hygeia***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***MPhA Mentor Award***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

☐ ***MPhA Honorary President***
Nominee _____
Address _____
City, State & Zip _____
Daytime Phone _____
Employment/Practice _____
Nominated by _____ Nominator's Phone _____

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

Awards Nominations
c/o Maryland Pharmacists Association
1800 Washington Blvd., Suite 333
Baltimore, MD 21230-1701

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2011 Awards Nominations
Maryland Pharmacists Association
1800 Washington Blvd., Suite 333
Baltimore, MD 21230-1701

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PHARMACY MARKETING GROUP, INC

AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

CAN YOU FILL IN ON SATURDAY?

Joe, the owner of Town Drugs, called and asked his friend Sandy to fill in next Saturday so Joe could attend a wedding. Joe and Sandy's friendship goes back many years, so Sandy agreed. Sandy has filled in for Joe maybe two to three times per year and Joe sends Sandy an IRS form 1099 at the end of the year. Unfortunately, Sandy misfilled a prescription on that Saturday and the patient was injured. Joe and Sandy had not contemplated what they would do in the event that an error occurred. What are the ramifications for this lack of planning?

From the owner's perspective: Joe has had a regular patient injured and he feels terrible about it. The patient may or may not want to transfer their prescriptions. Does Joe's store insurance policy cover this claim? It depends on Sandy's status. Joe's store policy covers his employees, but clearly Sandy is not an employee here. Joes isn't making any withholdings and isn't giving Sandy a W-2 at the end of the year. Other types of workers may be covered under the store's policy. They include temporary workers, leased workers and volunteer workers. Sandy is most likely an independent contractor, but Joe didn't check his liability policy before the loss to see if his store's policy covers independent contractors. If not, the store's policy won't cover this claim.

From the relief pharmacist's perspective Sandy filled in at Joe's assuming that Joe's store policy would cover her while working there. More than likely, the policy covering Sandy's regular employer will not cover Sandy while she is working at Joe's. So, very easily Sandy could wind up with neither policy covering her. Sandy could have purchased her own policy, but didn't think it was necessary since she was only filling in two or three times per year.

One possible result is that neither pharmacist has insurance coverage for this incident. Joe's pharmacy will be held liable for this error because it was the pharmacy that dispensed the errant medication. Sandy is liable because she is the pharmacist who misfilled the prescription. Joe and Sandy could end up fighting about who is going to take care of the injured patient and their long friendship could dissolve. Now, what should Joe and Sandy have done?

Planning for the unexpected takes a little time, but it is crucial in the event that something bad happens. Joe and Sandy should have been working under a written contract. The contract should clearly state Sandy's status with Joe's store (i.e., independent contractor, temporary worker, employee, volunteer, etc.). Depending on the agreed upon status, Joe should review his policy to verify coverage for Sandy's

activities. Joe should also make sure that Sandy has her own insurance policy as a fail-safe measure, regardless of whether he believes that his policy will cover her. Sandy would want to do this for her own peace of mind also. Joe and Sandy can also allocate risk in their contract and decide ahead of time who will be responsible should an error occur. This might have saved their friendship. Many times, such an allocation of risk could be covered under Joe's policy if it meets the definition of a covered contract. This is more likely to be true when the contract deals with the conduct of Joe's business. Which it does in this case.

Many pharmacists view requests to fill in as minor, friendly exchanges. No one expects bad things to happen. Unfortunately, lack of planning could result in them being a stressful, life-changing event. Take some time and plan ahead.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Morphine: To Dream or Not to Dream?

Lisa A. Flannery, Pharm.D. Candidate

Pain is as old as time, and everyone will experience this unpleasant feeling at some point in their lives. For centuries, people have been exploring methods to alleviate pain, finding much success along the way. Opium has been used for centuries as a postoperative analgesic and anesthetic, but the first actual recordings of its use as an analgesic did not occur until the 18th century. In 1784, London surgeon James Moore discovered that opium was better suited as an analgesic rather than an anesthetic. He recorded that "Opium…is highly expedient to abate the smarting of the wound after the operation is over, and to induce sleep; but the strongest dose we dare venture to give has little or no effect in mitigating suffering of the patient during the operation."[1]

In 1789, Scottish Surgeon Benjamin Bell released a statement, concurring with Moore's conclusions. "In general they prove most useful when given immediately after, when they very commonly alleviate that pungent soreness of which patients at this time usually complain; and by continuing to give them in adequate doses from time to time, we are often enabled to keep the patient easy and comfortable…."[1] It soon became common knowledge that opium had many benefits as a postoperative analgesic, but a pharmacist's apprentice from Germany took opium research a step further.

In 1805, Freidrich Serturner isolated a substance from opium he called "mekonsaure."[2] He tested this substance for activity on dogs and, much to his dismay, found that "mekonsaure" was inactive. He kept searching and came across a substance of "almost alkaline-like character" which he named "principium somniferum."[2] Serturner mixed it with mouse food for the mice in his cellar, as well as in dog food for stray dogs near the apothecary he worked in. He observed that "principium somniferum" produced drowsiness, sleep, and even death in some of the animals. Daring to take it to the next level, Serturner and three volunteers used themselves as research subjects. The four men took oral doses and experienced symptoms such as flushing, drowsiness, and "dream-like" states. Serturner concluded that "principium somniferum" was indeed active and renamed it "morphium" after the Greek god of dreams Morpheus.[1,2,3] "Morphium" became well-known in the medical community, and it was by French translation of Serturner's work that "morphium" took the name "morphine."

Oral morphine offered a highly effective method of quelling pain, and in the 1850s, the syringe and hypodermic needle introduced a new route of administration. Alexander Wood maintained that a local injection would alleviate pain; however, he noticed that his patients had difficulty remaining conscious. It was not until 1863 that subcutaneous morphine administration was recorded by James Paget, and in 1900, vascular surgeon Rudolph Matas was the first to administer epidural morphine. Although this method appeared to be effective in treating pain, epidural injections were not the preferred route at this time. During the 1970s, spinal administration resurfaced when researchers discovered the existence of centrally-acting opioid receptors. In the early 1980s, scientific literature finally confirmed the efficacy and safety of epidural morphine dosing.

Following the acceptance of epidural opioid use, submucosal, transdermal, and intra-articular opioid administration followed suit. The transdermal fentanyl patch was released in the late 1980s, and the first intra-articular morphine injection occurred in 1991. Today, patients can receive morphine injections following arthroscopic joint procedures for local relief of postoperative pain.

Morphine Today

Morphine was the first opium alkaloid to be isolated years and years ago, and it has served as a template for the discovery of subsequent opioids. Morphine is used extensively today and is FDA-approved for several types of pain such as chronic, obstetric, and postoperative pain. It is also utilized as an adjunct to anesthesia during surgery, for alleviating symptoms of myocardial infarctions, and as an adjunct for acute pulmonary edema secondary to cardiovascular problems.[4] Numerous clinical trials are under way regarding the use of morphine in cancer patients, as

it is commonly prescribed to allay cancer pain. However, morphine and other opioids have not proven themselves useful for relieving neuropathic pain.

Morphine certainly has valuable uses for pain and other health conditions, but it also comes with its share of adverse effects. Like all opioids, morphine causes respiratory and cardiovascular depression. Patients may experience symptoms of orthostatic hypotension, syncope, and in severe cases, cardiac arrest. Morphine also impedes gastric emptying, which may cause nausea, vomiting, and constipation. For this reason, morphine and other opioids are commonly prescribed in tandem with a combination of laxatives and stool softeners.

Patients taking morphine may find that they become tolerant to its effects. This is why it is imperative to obtain a complete medical history. Opioid-naïve patients usually require smaller morphine doses to start, while those who are opioid-experienced may need higher doses due to the development of cross-tolerance. When counseling patients, it is crucial for pharmacists to educate patients on opioid tolerance and what to do if they feel the medication no longer alleviates their pain. When counseling patients about tolerance, pharmacists would be remiss by not mentioning the abuse potential. Unfortunately, drug-seeking behavior is at an all-time high, and opioids such as morphine are in high demand. Pharmacists must remain vigilant regarding drug diversion in order to prevent illegitimate opioid use.

Morphine is an excellent pain-relieving drug with many indications. It has been used, in some form, for centuries for postoperative pain and has found many other uses since its discovery. Freidrich Serturner was a pioneer in the field of medicine, and he began a trend of medication research he probably never dreamed of. Clinical trials are conducted continuously to refine and further the uses of morphine, and delivery methods are always improving. Morphine has been around for hundreds of years because of its beneficial therapeutic effects. If history is the best predictor of the future, morphine will be here to stay.

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"Medication Therapy Management (MTM) Light" Series: Practical Guidance for Maryland Pharmacists to Develop and Implement MTM Services

In a continued effort to meet Maryland pharmacists' needs, the Professional Development Committee has initiated an MTM light series to assist pharmacists incorporating MTM services into current pharmacy practice. With an introductory article (1) in the June-July-August 2010 issue of the journal, there will be a series of articles highlighting a variety of topics, including: (2) collaborating with physicians; pharmacist-physician relationships, (3) conducting a SWOT analysis; obtaining pharmacist's credentials and National Provider Identification (NPI) for clinical services, (4) documenting, monitoring and tracking patient care, and (5) obtaining compensation/reimbursement for clinical/cognitive services. Look for these articles in current and future issues of the journal.

Article 2

Establishing a Medication Therapy Management (MTM) Practice: Building Pharmacist-Physician Relationships

Kristen M. Fink, PharmD, BCPS, CDE and Rosemary E. Sassic, PharmD Candidate

Medication Therapy Management (MTM) is on the rise. Not only are MTM services beneficial for our patients and physicians, they are advancing the pharmacy profession. We know that it is vital to jump on this band wagon, but there is one important question – how do we start an MTM practice? A first essential step is to establish collaborative relationships with physicians.

As pharmacists, we speak with physicians and other practitioners on the telephone daily, which can provide opportunities for relationship-building. These conversations are potentially the beginnings of a successful implementation of MTM practice. The best way to gain the trust and support of local physicians for an MTM practice is to begin with the ones that we already have a relationship with. We can start by paying attention to our patients and their prescriptions to identify prevalence in disease states and medication use where we can offer MTM services. It may also be important to conduct a background search on each physician's practice site. Each physician will want to know how *you* can help *them* with their patient care.[1] A physician's practice may have a specific patient population with specific needs. If you have obtained credentials or gained experiences in a particular specialty, you can use that to your advantage.[2,3] Once you identify a need in the community, you can turn that into your niche.

Having determined which physicians you want to approach, it is time to assemble your materials and visual aids (e.g. brochures, flyers, etc). First, be ready to explain the concept and elements of MTM (i.e. medication therapy review, personal medication records, etc.). Physicians are also busy, so do not provide too much paper. A brief, one-page summary of MTM, and your personal contact information (i.e. business card) in an envelope or folder are sufficient. You may also want to create flyers with a patient–friendly definition of MTM at the appropriate health literacy level (i.e. middle school reading level) and the pharmacy contact information that the physician could give to patients while they are in the office. Remember to keep copies for yourself.

The next step is to outreach to physicians. Let them know that you take care of many of their patients at your pharmacy and you would like to set up a time to speak with them in person. On the day of your appointment, arrive early and introduce yourself to the physician and office staff. Ask the physician if he/she has heard of MTM and what he/she has heard about MTM. If the information is inaccurate, gently correct the misconceptions then pitch your idea. Think of yourself as a salesperson. Tell the physician why you are interested in their practice and how MTM can fit into and enhance his/her patient care. It is important that you are prepared and deliver your message clearly so that the physician understands your goals. Physicians are generally busy so keep your presentation brief. Give the physician a copy of the MTM summary, ask if they have any questions about the process, and thank them for their time.

After your visit to the physician's office, call the physician about a week later and ask if he/she has questions related to MTM and if he/she is interested in the collaboration. Express to them that you are looking forward to working with them. You may consider offering to assist the physician on a trial period of a month or by monitoring a select number of patients

and exchanging your therapeutic regimen suggestions with the physician. This will allow the physician time to observe your practice as well as develop their confidence in your skills. Remember, the physicians who you will be speaking with may not be familiar with MTM services and may not automatically trust that you are qualified for this responsibility. Try not to take it personally; new ideas and practices often require an adjustment period.

Once you have worked with a patient and are ready to communicate your recommendations to the physician, you may find it helpful to use an SBAR approach when calling the physician regarding an identified problem. First, explain the Situation (S). For example: Mr. X reported to the pharmacy today with a fasting blood sugar reading of 250mg/dL. Second, provide the Background (B): Mr. X confirms that he took his 50 units of Lantus insulin yesterday evening the way that he always does. His diet is consistent, and he reports that his blood sugar is always around 250mg/dL in the morning. Third, make an Assessment (A): Mr. X appears to be not at goal on his current dose of 50 units of Lantus insulin. Fourth, suggest a Recommendation (R): I recommend that Mr. X's Lantus insulin dose be increased to 55 units every evening. Mr. X should check his blood sugar at least once daily and report readings back to me in one week for follow-up. By using the SBAR method of communication you will be providing the physician with necessary information to make a decision about your plan in a clear and concise manner.

Opening the lines of communication to establish relationships with physicians for an MTM practice can be a difficult task to undertake. Always remember to have confidence in yourself and your abilities so that you may successfully be a part of this physician's practice. Also, if you plan on distributing literature to the physician, keep it short and easy to read. Like us, they do not have the time or desire to read through long articles. Get your point across; show them that you are an asset as a drug expert and that Medication Therapy Management is a great opportunity for inter-professional collaborations. Once you have one door opened for MTM, the rest will fall into place. Be on the lookout for more practical guidance on how to start your own MTM practice in upcoming MPhA journal articles.

For questions regarding MTM opportunities or suggestions, please contact MPhA Professional Development Committee Co-chairs Kristen M. Fink, PharmD, BCPS, CDE, Clinical Pharmacy Specialist, Kaiser Permanente and Fink's Pharmacy at fink462@hotmail.com or Hoai-An Truong, PharmD, MPH, Assistant Director of Experiential Learning at University of Maryland School of Pharmacy, and MTM Pharmacist at Mercy Health Clinic, Primary Care Coalition of Montgomery County, at htruong@rx.umaryland.edu

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Continuing Education

Liver Disorders: Part I: How to Spot a Patient with Hepatic Dysfunction

Lauren M. Hynicka, Pharm.D., BCPS
University of Maryland School of Pharmacy
Assistant Professor of Pharmacotherapy

Learning Objectives:

After reading this article and completing the assessment questions, the participant will be able to:

1. *Identify the three major physiologic functions of the liver.*
2. *List and define common presentations associated with liver disease.*
3. *Describe dosing strategies for medications used to treat common liver disorders, and how this differs from dosing strategies for other disorders.*

What makes the liver so important? The liver is the largest organ in the body and performs more than 200 functions. The cells responsible for the functions of the liver are the hepatocytes. Hepatocytes carry out three major classifications of liver functions: metabolic regulation, hematologic regulation and bile production. The blood supply to the liver is extensive allowing it act as the body's filter (metabolic regulation) to remove both nutrients and toxins prior to reaching systemic circulation. The liver also synthesizes numerous proteins including both albumin and clotting proteins (hematologic regulation). Albumin is a component of the serum and helps to maintain fluid in the intravascular space (arteries) rather than leaking into the surrounding tissues to cause edema. Clotting proteins II, VII, IX and X are produced in the liver and are responsible clot formation. Bile produced in the liver is excreted into the duodenum and the bile salt component aids in the breakdown of dietary lipids. In addition to excretion into the duodenum bile is stored in the gallbladder for future use. Destruction of liver cells by multiple disease states results in replacement of normal liver tissue by collagen and other matrix proteins; this change in the composition of the liver is referred to as cirrhosis. Cirrhosis prevents the liver from performing its usual functions and can result in numerous complications, and is potentially fatal.

Cirrhosis is a problem worldwide, particularly in the United States. The most common causes of cirrhosis are chronic alcohol consumption and chronic viral hepatitis B, C and D.[1] The exact prevalence of cirrhosis in the United States is unknown, however it is estimated that hepatic dysfunction is responsible for approximately 27,500 deaths each year and ranks as the 12th leading cause of death. Numerous complications including ascites, spontaneous bacterial peritonitis (SBP), hepatic encephalopathy, portal hypertension and variceal hemorrhage, contribute to the morbidity and mortality associated with hepatic dysfunction. Hepatic failure can also lead to alterations in the ability of the liver to metabolize medications and subsequently necessitate dosing adjustments. Identifying patients in the community pharmacy setting with hepatic dysfunction may seem challenging without the availability of laboratory values. With an understanding of the medications used to prevent and treat the complications of hepatic dysfunction, a medication profile can reveal a lot about a patient and provide clues to patients who have cirrhosis. Throughout the remainder of the document we will review the complications of cirrhosis, including ascites, spontaneous bacterial peritonitis (SBP), hepatic encephalopathy and

variceal hemorrhage, and their treatment modalities.

Ascites is the build-up of fluid in the peritoneal cavity that is a direct result of increased resistance in the liver secondary to hepatocyte destruction and the inability to maintain fluid in intravascular space due to decreased albumin. The medical management of ascites consists of a loop diuretic in combination with a potassium sparing diuretic. The most commonly prescribed and first-line regimen is the combination of furosemide and spironolactone. Diuretic therapy is used in numerous other disease states, including heart failure, edema and hypertension. However, in the treatment and prevention of ascites there are specific ratios of these diuretics that help identify a patient who is on therapy as a result of hepatic dysfunction. The specific ratio you should be on the look-out for is 100 mg of spironolactone to 40 mg of furosemide. Both diuretics are administered once daily and the doses can be adjusted to a maximum of 400 mg of spironolactone in combination with 160 mg of furosemide. When increasing the dose the 100:40 ratio is maintained and typically referred to as step therapy (table 1). The spironolactone is really the work-horse of this combination and maintaining the above ratio has been shown to maintain normokalemia for these patients. The other dose-limiting side-effect for spironolactone is gynecomastia. Gynecomastia is the development of abnormally large mammary glands in males resulting in breast enlargement. If this occurs an alternative therapy that can be used is amiloride 5 to 20 mg orally once daily.[2]

Spontaneous bacterial peritonitis (SBP) is a common complication that develops as a result of the accumulation of ascitic fluid in the peritoneal space. An episode of SBP requires admission to the hospital for diagnosis and treatment with intravenous antibiotics. At 1 year after the first episode of SBP the chance of a subsequent episode of SBP is 40 to 70% and carries a mortality risk of 50 to 70%. The morbidity and mortality associated with SBP has lead to the routine prescribing of antibiotic prophylaxis in patients who have ever had an episode of SBP. The specific regimen that is recommended for secondary prevention of SBP is ciprofloxacin 750 mg orally once weekly and should be continued for the life of the patient or until they receive a liver transplant. While ciprofloxacin is a commonly used antibiotic to treat a multitude of infections, the dosing for SBP prophylaxis is certainly unique and is yet another way to identify a patient who may have hepatic dysfunction.[3]

Hepatic encephalopathy commonly occurs in patients with hepatic dysfunction likely secondary to the inability to clear ammonia from the body. The buildup of ammonia subsequently alters neurotransmission in the brain to cause symptoms such as confusion, asterixis, and in severe circumstances, coma. The most commonly used therapies to treat hepatic encephalopathy include lactulose and rifaxamin. Lactulose is considered first-line therapy and is a non-absorbable disaccharide that works by binding to the ammonia in the small intestine and is then excreted in the feces. In general, the lactulose dose is 10 to 20 grams several times per day (usually every 4 to 6 hours) and should be titrated to achieve 2 to 3 soft bowel movements per day. Rifaxamin is a much more expensive therapy but has been proven to be non-inferior to lactulose in the treatment and prevention of hepatic encephalopathy. Rifaxamin is an nonabsorbable antibiotic that eliminates urease producing bacteria from the small intestine and thereby decreases the amount of ammonia produced. The dose of rifaxamin used in the treatment of hepatic encephalopathy is 400 mg every 8 hours. The only other FDA approved indication for rifaxamin is the treatment of traveler's diarrhea which requires a dose of 200 mg every 8 hours.[4]

Variceal hemorrhage is the final complication of hepatic failure. Varices can form at any point in the gastrointestinal tract, but are most commonly found in the esophagus. Varices form as a result of increased pressure within the portal vasculature that feeds the liver. This elevated pressure, similar to the discussion of ascites, is the result of increased resistance within the liver. The resulting varices are actually collateral blood vessels that have formed as a result of the increased portal pressure. Unfortunately varices have a high propensity to bleed and when they do bleed carry a 6 week mortality rate of approximately 20%. While varices themselves have a high likelihood to bleed

due to their superficial nature, patients with liver disease are also at increased risk for bleeding because of the decreased production of clotting proteins discussed in the introduction. When a patient is first diagnosed with cirrhosis an esophagogastroduodenoscopy (EGD) should be performed to screen for variceal formation. In order to prevent a variceal bleed, patients in whom varices are found will be started on a non-selective β-blocker, nadolol 40 mg orally once daily, propranolol 20 mg orally every 12 hours or carvedilol 6.25 mg orally every 12 hours. Nadolol and propranolol have been studied more extensively in the prevention of variceal bleeding and are more commonly prescribed for this indication than carvedilol. A non-selective β-blockers is preferred because blockade of β_2 receptors and α_1 receptor stimulation result in decreased portal pressure. While the use of β-blockers is common place in patients with hypertension and history of myocardial infarction, propranolol and nadolol are not frequently used for cardiac indications and could clue you in that a patient taking one of these two medications may have hepatic dysfunction.[5]

In conclusion, cirrhosis is a significant problem in the United States with numerous potential complications. The doses of medications and the specific medications from within drug therapy classes used in the treatment and prevention of hepatic failure complications are unique compared to their use in other common disease states. An understanding of the medications used in the treatment and prevention of hepatic failure complications can help to provide clues as to which patients have hepatic dysfunction. Look for a subsequent issue to learn about which medications require adjustment in hepatic failure.

Table 1: Step Therapy with Diuretics for the Treatment and Prevention of Ascites

	Furosemide dose	Spironolactone dose
Step 1	40 mg	100 mg
Step 2	80 mg	200 mg
Step 3	160 mg	400 mg

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Continuing Education Quiz

This month's questions are taken from the article on "*Liver Disorders: Part I: How to Spot a Patient with Hepatic*". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230-1701. There is no charge for this quiz for MPhA members (non-members $ 10.00). Program release date: January 3, 2011. *Program expiration date: March 31, 2012.* This program provides for 1.00 contact hour ((0.1 CEU) of continuing education credit. A continuing education certificate will be sent to you within six to eight weeks. ACPE# 0144-0000-11-007-H01P Please type or print clearly.

Name_____

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Date Completed _____

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

1. The most common causes of hepatic failure in the United States are:
   a. Chronic hepatitis A, B and E
   b. Chronic hepatitis B,C and D
   c. Chronic alcohol use
   d. Both B and C

2. The spironolactone to furosemide ratio used in the treatment of ascites is which of the following?
   a. 40:100
   b. 25:100
   c. 100:40
   d. 100:20

3. Maintaining the ratio of spironolactone to furosemide is recommended for which of the following reasons?
   a. It maintains normokalemia
   b. Better diuresis occurs
   c. It has been shown to decrease mortality
   d. It has been shown to decrease morbidity

4. Which of the following is a limiting side effect when spironolactone is used to treat ascites?
   a. SBP
   b. Gynecomastia
   c. Hepatic encephalopathy
   d. Variceal hemorrhage

5. When a patient receiving spironolactone experiences a therapy-limiting adverse effect, which of the following would be an appropriate alternate agent?
   a. Amiloride
   b. Torsemide
   c. Metolazone
   d. Bumetanide

6. Which of the following is the dose of ciprofloxacin used as secondary prophylaxis for spontaneous bacterial peritonitis?
   a. 250 mg po every 12 hours
   b. 500 mg po every 24 hours
   c. 250 mg po every other day
   d. 750 mg po once weekly

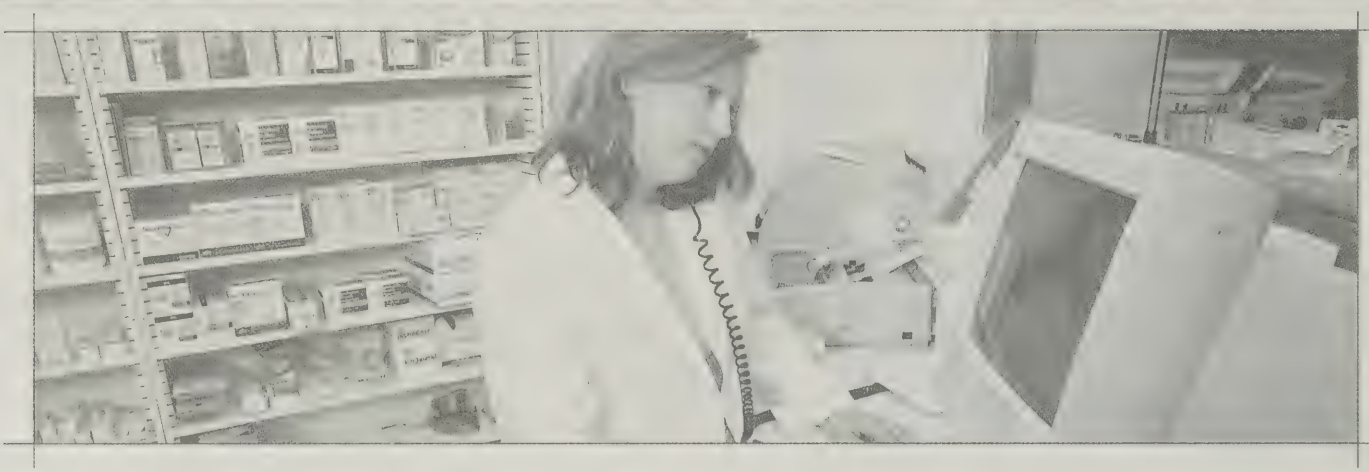
7. What is the appropriate treatment duration for spontaneous bacterial prophylaxis (SBP)?
   a. 1 week
   b. 2 weeks
   c. 6 weeks
   d. life-long

8. What rifaxamin dosing should be used to treat hepatic encephalopathy?
   a. 200 mg po every 8 hours
   b. 200 mg po every 12 hours
   c. 400 mg every 8 hours
   d. 400 mg every 12 hours

9. When titrating lactulose to treat hepatic encephalopathy, what is the targeted bowel movement frequency?
   a. A bowel movement daily
   b. 2-3 bowel movements daily
   c. 4-5 bowel movements daily
   d. One bowel movement every 2 hours

10. Which of the following β-blockers are recommended for the primary or secondary prevention of variceal hemorrhage?
    a. Nadolol
    b. Metoprolol tartrate
    c. Bisoprolol
    d. Atenolol

Is your pharmacy running *you*?



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VOLUME 87 NO. 1

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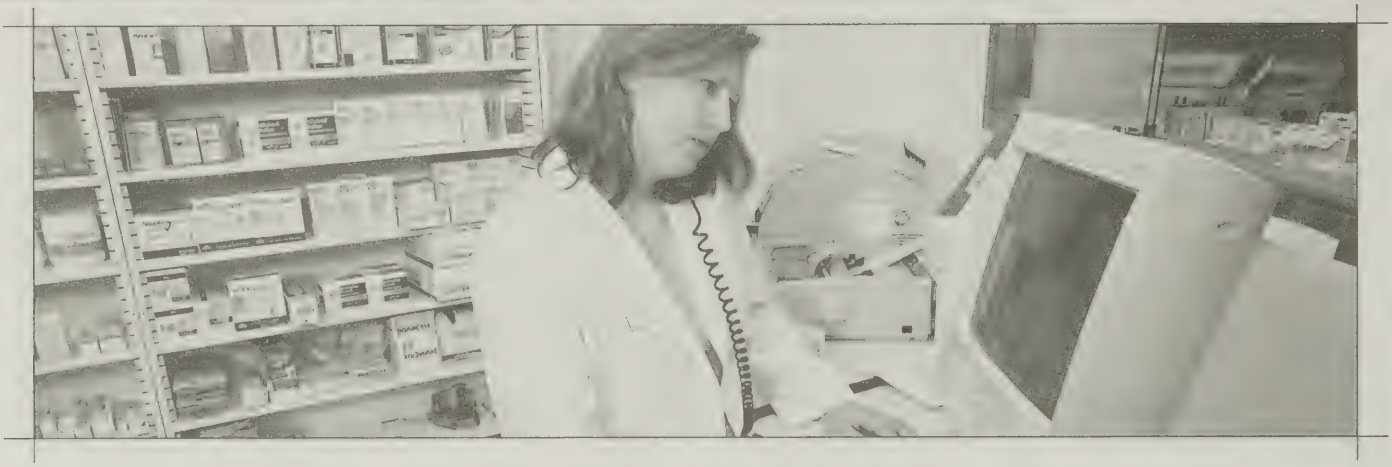

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Empowering Healthcare

President's Message

Change is Difficult (and other sayings)…

Carol Stevenson, Pharm.D.
President

Change is pretty much a constant in the world of healthcare, actually in the world period. We are asked to **go with the flow, chill out, get with the picture, jump on the train, man up**, and so on! Change may be difficult, but this organization has **caught the ball and is running with it**.

What a **whirlwind pace** MPhA kept during this year. We turned the fall Board of Trustees meetings into **road shows**, having meetings hosted by both Notre Dame and the University of Maryland at Baltimore. We are grateful for their support and academic expertise. We also had the opportunity to welcome the students and staff of the new University of Maryland Eastern Shore, and look forward to their involvement.

For those who did not attend the Mid-Year meeting that was held in conjunction with Maryland ASCP at the Maritime Academy, you **missed the boat**! We had a stellar program with meals just like the buffet on the **Love Boat**! Working with another organization, developing dual tracks, and even finding the building **brought us out of our comfort zone**. It is not so easy to change the way we have been doing things, but I want to compliment the entire staff and convention committee. They **jumped into the fray** and **made it work**! We had an excellent turn out, and all who worked on the event should be very proud. Legislative Day brought a **delightful problem**; too many people! That was **null problemo** for the Pharmacy Coalition. They just rented the biggest auditorium in Annapolis and **moved forward**! Things worked very well, and all who attended got to participate in the law making process. I was so proud of all the pharmacists who took a day off from work to talk to their legislators, and all the students who arrived in white coats! Pretty impressive! The students who came from the University of Maryland Eastern Shore not only arrived on time at 7 AM in Annapolis, but also stayed for the Board of Trustees that evening. **Kudos**!

Just when we thought we could **rest on our laurels**, the Professional Development Committee came up with a little idea. In conjunction with APhA MTM training, the committee organized the first ever MTM Summit. It was to be a modest meeting with a few speakers, a sack lunch, an informal round table opportunity, and a small reception for networking. **Not so much** modest! Speakers included leaders from APhA, a Pennsylvania MTM entrepreneur, Outcomes, University of Minnesota MTM program, and our own P3 program. Participants came from Michigan, Florida, Virginia, Delaware, Pennsylvania, New Jersey, and West Virginia. The catered lunch was wonderful, the round table participants and exhibitors enthusiastic, and the reception **absolutely fabulous!** Student and committee members **pitched in** to set up tables and act as hosts to the many attendees. **A good time was had by all**! Other state organizations have expressed an interest in partnering with us on MTM programs in the future! It looks like the **first ever** summit **will certainly not be the last**!

So is there more for us to do? Of course, we have a lot of **challenges**. Trustees need to reach out to members and non-members to **engage them** in our mission. They are the **face** of the organization. Student members from all our schools have the opportunity to work together and learn from each other. Members can get involved in so many ways. Attending a mid-year meeting, convention, crab feast, MTM summit, golf tournament, wine tasting, legislative day, or trustee's meeting are just a part of the opportunities available. Educational, entrepreneurial, philanthropic and social **opportunities abound. Networking is everywhere**. Get your **blood flowing**. Get involved. Get your friends involved. If you are concerned about all the changes in healthcare and how they will affect your practice, remember that **time is of the essence**. Get involved in MPhA. It is your organization. **Don't be part of the healthcare problem, be part of the solution! That's all folks!**

AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

YOU'VE BEEN SERVED!

The day that you had hoped would never come has come. The sheriff makes his way through the store, with papers in his hand, heading towards the prescription counter. The sheriff says, "Chris, I've got something for you." The sheriff hands you the summons and complaint and walks out of the store. A summons is the notice that a suit has been filed against you. A complaint is the actual lawsuit. Now what do you do?

The most important thing is to not ignore it. This event, service of process, is the start of a procedure that is very time-sensitive. Unfortunately, some defendants read through the complaint and conclude that it is either a bogus case or just a ploy to extract money from them. The worst thing you can do is to toss it aside or throw it in a drawer and forget about it. This is not something that is going to go away. Ignoring it is only going to cause you more problems. In fact, the clock started when the sheriff handed Chris the summons.

Court rules prescribe the time frame within which some sort of response to the summons must be made. Depending on the jurisdiction, this is typically 20 or 30 days, although there are some other limitations out there. If nothing is filed with the court before this time expires, the plaintiff may be able to file for a default judgment. A default judgment essentially says, "You failed to respond, you lose." If the plaintiff gains a default judgment, they can then begin to try to collect the money from you. The worst thing about a default judgment is that there is no deliberation on the facts or the issues of the case. You might end up paying on that bogus case that you tossed into the desk drawer.

The most typical response to a summons and complaint is to file an answer. The answer addresses all of the allegations made by the plaintiff. The responses are usually one of three possibilities; admission, denial, or not enough information. With an admission, you admit that the allegation is true. With a denial, you deny that the allegation is true. The third response is used when you don't know enough about the allegation to admit or deny it. For litigation purposes, this is treated as a denial. A response needs to be made for each and every allegation in the complaint. The answer is also the place where affirmative defenses are raised. These are legal defenses that counteract the allegations against you. For example, raising truth as a defense to slander or libel.

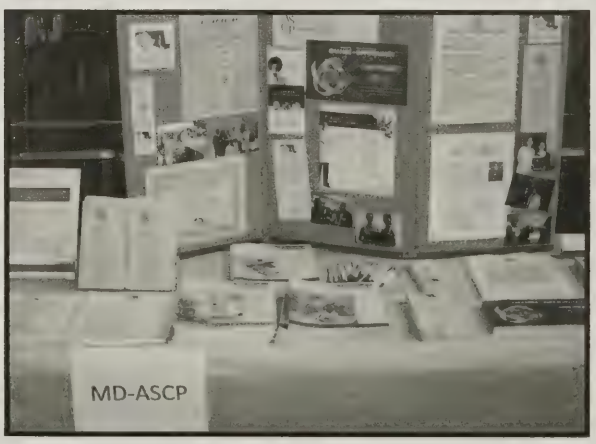
However, there are circumstances when other filings are made instead of an answer. These are generally motions that raise a particular issue to the court. The purpose of these motions is to contest certain issues

prior to actually working on the substance of the case via the answer. If you are successful on these issues, many times the case is thrown out and there is no need to work on the substance of the case. The issues contested here can include the lack of jurisdiction by the court, the case is filed in the incorrect venue, the summons and complaint was improperly served, the case failed to name the proper parties, or the case is a duplicate of a previously filed case in another court.

It takes time to evaluate the allegations, decide whether to file an answer and/or a motion and to decide what allegations need to be admitted or denied. Timeliness is your most valuable asset. Don't be an ostrich when you are served. Sticking your head in the sand won't make it go away and ignoring it could result in some serious negative ramifications for you. Call your attorney and/or insurance company as soon as possible. The more time they have to work on your response, the better it will be.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Inaugural Annual Maryland Medication Therapy Management (MTM) Summit: A Successful Collaboration among State Associations and Schools of Pharmacy



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FINANCIAL FORUM

This series, **Financial Forum**, is presented by Pro Advantage Services, Inc., a subsidiary of Pharmacists Mutual Insurance Company, and your State Pharmacy Association through Pharmacy Marketing Group, Inc.,a company dedicated to providing quality products and services to the pharmacy community.

FIVE INVESTMENT MISTAKES YOU DON'T HAVE TO MAKE

It's easy to have confidence in investments made during bull markets as share prices climb and any losses from poor decisions are usually recovered fast. But in times of increasing market volatility, mistakes tend to be magnified and many investors may lose confidence in their decision making. Let's take a quick look at some of these common mistakes that can generally be avoided.

1. Timing the Market

During a downturn in the market, investors who regularly contributed to their portfolios when the market was rising often decide to stop investing until conditions improve. This can prove to be a costly mistake.

Not only is it impossible to time the ups and downs of the market with consistent success—by sitting on the sidelines during a down market, you could miss out on an opportunity to buy stocks and other investments at low prices. In good times and bad, long-term investors should carefully consider the merits of dollar-cost averaging. By continuing to make investments of the same dollar value at regular intervals, investors can buy more shares when prices are low, fewer when prices are high.

A periodic investment plan such as dollar-cost averaging does not assure a profit or protect against a loss in declining markets. Also, since such a strategy involves continuous investment, investors should consider their ability to continue purchases through periods of low prices.

It is also important to continue to make contributions to your 401(k) plan or similar employee-sponsored retirement plan. These contributions often "earn" matching funding from your employer—providing additional earnings potential.

2. Skipping the Research

Determining whether an investment is appropriate for your portfolio requires research. There are more companies and investment products to invest in today than ever before, but determining which investments have potential for growth requires information.

Before making an investment, it's helpful to evaluate it in the context of comparable opportunities. At a minimum, you should find two articles (from different authors) about the company or investment product and review the company'swebsite. Both the investor relations section and news announcements found on the website can provide useful information. You should also review financial statements and carefully investigate anything that looks vague or unusual.

In addition to its role in making sound investment decisions, research can also help you to feel comfortable with the holding in spite of temporary ups and downs.

3. Chasing Past Performance

Yesterday's hot stock may have already topped out. Today's innovative start-up may not have the wherewithal to stay in business. So it's important to make investment decisions based on more than past performance and a few headlines. Investments should be made with the future in mind. If there is strong growth potential, and the fundamental likelihood of the company's success looks good to you, then it may make sense to invest even after a successful run. Keep in mind, however, that past performance is no guarantee of future results.

4. Trading Too Often

Frequent trading will likely reduce the total return of your portfolio. In addition to the trading fees and taxes that are incurred, frequent trading does not reflect a long-term outlook and thoughtful investment strategies. Typically, neither timing the market nor running scared enhances your portfolio's performance. In fact, a study from the University of California found that the average annualized return of retail investors who traded most frequently was seven percent lower than the return of those who traded least frequently.

5. Selling Low, Or Not At All

Before selling a stock or investment product that has tumbled, it's important to do some additional research to understand why it dropped. This research will help you anticipate the holding's potential for recovery. If the setback appears to be triggered by a temporary problem that can be easily overcome, you may even want to consider buying more while the price is low.

Conversely, it's also important to know when to take a loss. It hurts to lose money, but a little pain now may pay off in the long run. If your company or investment relies on an industry that is likely to be weak for several years, consider selling to avoid any additional losses.

Learning from your own past mistakes, as well as from those made by others, is an important step toward becoming a better investor. To find out more about avoiding these and other mistakes often made by investors, contact your financial advisor.

Provided by courtesy of Pat Reding, CFP™ of Pro Advantage Services Inc., in Algona, Iowa. For more information, please call Pat Reding at 1-800-288-6669.

"Medication Therapy Management (MTM) Light" Series:
Practical Guidance for Maryland Pharmacists to Develop and Implement MTM Services

In a continued effort to meet Maryland pharmacists' needs, the Professional Development Committee has initiated an MTM light series to assist pharmacists incorporating MTM services into current pharmacy practice. With an introductory article (1) in the June-July-August 2010 issue of the journal, there will be a series of articles highlighting a variety of topics, including: (2) collaborating with physicians; pharmacist-physician relationships, (3) conducting a SWOT analysis; obtaining pharmacist's credentials and National Provider Identification (NPI) for clinical services, (4) documenting, monitoring and tracking patient care, and (5) obtaining compensation/reimbursement for clinical/cognitive services. Look for these articles in current and future issues of the journal.

Article 3

Establishing a Medication Therapy Management (MTM) Practice: Getting Started – Are You Ready for MTM?

Andrew N. Michaelson, PharmD

In this entry of the *MTM Light* series, we look at the essential preparations in setting up an MTM practice. Registration with the Centers for Medicare & Medicaid Services (CMS) and receipt of a specific number required for billing will be covered, as well as a hands-on personal exercise that prepares the pharmacist for potential challenges and opportunities for growth in their practice.

Obtaining a National Provider Identifiers (NPI)

The National Provider Identifier (NPI) is a number required by the Centers for Medicare & Medicaid Services (CMS) in order to bill online for health care services. As an MTM pharmacist, it is imperative for you to have this identifier to submit and receive reimbursement for your MTM services.

The application process can easily be completed online and takes about 15 minutes. The main pieces of information that you will need are your current licensing information, including license number, as well as all of your address and other contact information for your mailing and business locations. You will be able to choose from among different specialties of pharmacy, including nutritional support, oncology, clinical pharmacist, or you can also select the more general 'pharmacist' classification. Once you have submitted your application online, you will have the option to print your application, and there is a waiting period for you to receive your identifier. Once you have obtained this number, you will be able to bill Medicare for MTM services. It took about a week for my number to arrive following my application.

The directory of providers is available to the general public, meaning you can search anyone's name in order to determine if they have an NPI number. This database is important in all settings of pharmacy, both in the community as well as consulting and MTM. Other contact information is also available through the database, so by searching for your colleagues you can also get a sense of what information will be visible when someone searches for you. *For more information, visit the NPI website: https://nppes.cms.hhs.gov/NPPES/Welcome.do*

Conducting a "Strengths, Weaknesses, Opportunities, and Threats" (SWOT) Analysis

Integrating Medication Therapy Management (MTM) service to an existing pharmacy operation, or initiating a new program, involves planning and preparation. How will the practice benefit the community? Who is the target audience? How will you market your practice, and how will it be different than existing programs? It is important to research and have a sense of the answers to these questions as part of the preparation prior to implementing an MTM service. A "Strengths, Weaknesses, Opportunities, and Threats" (SWOT) analysis is a systematic, organized way to help develop business plans and determine best strategies for a new practice.

A SWOT analysis involves looking at both internal and external factors to determine what affects your proposed practice plan. Internal factors include strengths and weaknesses, while external factors include opportunities for the practice as well as the threats to it. The following section provides a brief explanation of the different aspects of a SWOT analysis, an important hands-on exercise for starting a new MTM practice.

The internal factors should be examined first. The "S"trengths and "W"eaknesses are the sections that look at various characteristics of the pharmacy environment where MTM services will be offered, such as the patient population that lives in the area of the pharmacy's location, the staff at the pharmacy, interpersonal relationships with providers who could refer patients to the MTM service, and many other factors. The internal factors can be under your control, whether through marketing, location, or staff training, for examples. Additionally, these internal factors can be greatly affected by how you prepare yourself for provision of MTM services. Additional training and certifications (i.e. APhA-ASCP MTM national certificate training program) are certainly strengths. If MTM

services will be offered as part of an existing community pharmacy, training other staff members in paperwork, recruitment of new patients, and acceptance of the new responsibilities that will be a new part of their daily tasks will be part of the preparation. Involving your staff in the process is a vital part of MTM service, and current staffing situations could be considered strengths or weaknesses in conducting a SWOT analysis. An honest analysis of strengths and weaknesses is a good basis for determining improvements prior to implementing an MTM service.

Once internal factors have been considered, the focus shifts to external factors. These are not directly under your control but can have potential impact on an MTM service. Opportunities are situations which can greatly increase the effectiveness and viability of an MTM service, or can potentially increase the profitability and sustainability of the business. Threats can be situations keeping patients from experiencing MTM service. Examples of threats include market saturation, lack of providers interested in referrals, or language barriers in the particular community you are trying to reach. Having a good sense of opportunities and threats to the idea and plan for a new MTM service will help you best prepare for a successful practice.

The upcoming articles in the *MTM Light* series will look at patient care, why documenting and monitoring is the backbone of MTM, and compensation or reimbursement for services for your established MTM practice.

The author acknowledges that some information regarding the SWOT analysis were adapted from the American Pharmacists Association (APhA) and American Society of Consultant Pharmacists (ASCP) *Delivering Medication Therapy Management Services in the Community: A National Certificate Training Program for Pharmacists* (2009 edition).

For questions regarding MTM opportunities or suggestions, please contact MPhA Professional Development Committee Co-chairs Kristen M. Fink, PharmD, BCPS, CDE, Clinical Pharmacy Specialist, Kaiser Permanente and Fink's Pharmacy at fink462@hotmail.com or Hoai-An Truong, PharmD, MPH, Assistant Director of Experiential Learning at University of Maryland School of Pharmacy, and MTM Pharmacist at Mercy Health Clinic, Primary Care Coalition of Montgomery County, at htruong@rx.umaryland.edu.

Inaugural Annual Maryland Medication Therapy Management (MTM) Summit: A Successful Collaboration among State Associations and Schools of Pharmacy

The first Maryland Medication Therapy Management (MTM) Summit on March 5, 2011 was a huge success with over 160 participants from Maryland, across the Mid-Atlantic region, and as far as Minnesota, Michigan, and Florida. In fact, several state pharmacy association officers from DE, PA, and NJ expressed interests in future collaboration with Maryland. The summit was presented by the **Maryland Pharmacists Association (MPhA) Professional Development Committee** and the University of Maryland School of Pharmacy (UMSOP) and was co-sponsored by the Maryland Chapter of the American Society of Consultant Pharmacists (MD-ASCP), College of Notre Dame of Maryland School of Pharmacy, Maryland Pharmaceutical Society (MPhS), Maryland Pharmacists Association Foundation, Outcomes Pharmaceutical Health Care, and University of Maryland Eastern Shore School of Pharmacy.

The Keynote address on MTM and Health Care Reform was presented by Brian Gallagher, RPh, JD, Senior VP of Government Affairs at the American Pharmacists Association (APhA). James Owens, PharmD, Senior Director of Professional Practice at APhA presented a session on MTM Perceptions and Current Status. Other sessions included MTM and Improving Public Health, Developing a Business Model, Maryland P3 Program, MTM Fairview Program in Minnesota, and a report from Outcomes Pharmaceutical Health Care. The afternoon included Roundtable sessions on MTM in various settings. Exhibits included posters and sponsor booths. The first successful MTM summit, with less than 5 months of planning, concluded with a reception at the MPhA Headquarters at Montgomery Park.

Special thanks to MPhA President Carol Stevenson, Past President and Treasurer Matt Shimoda, Past President Paul Holly, Historian Doug Campbell, Executive Director Howard Schiff, Office Manager Elsie Prince, Administrative Assistant Nancy Ruskey, as well as student coordinators APhA-ASP President Janessa Smith, Sheryl Thedford, and Chai Wang from UMSOP. Appreciation also goes to over 20 professional development committee members and over 30 student volunteers from all 3 schools. Without committee members and student volunteers, the event would not have happened. For more information, please contact co-chairs Kristen M. Fink, PharmD, CDE, at fink462@hotmail.com or Hoai-An Truong, PharmD, MPH, at htruong@rx.umaryland.edu.

ULCERS: The Real Culprit

By Amanda Dacey, PharmD Candidate 2011
University of Maryland School of Pharmacy

HISTORY

The discovery of hydrochloric acid in the gastrointestinal tract in the early 1820's led to the belief that acid was the cause of peptic ulcers. In order to decrease acid in the stomach, patients were instructed to watch their diet, never eat when tired, and to rest. If these lifestyle changes did not work, atropine was the go to drug at the time since anticholinergic medications decrease motor and secretory functions of the gastrointestinal tract. Atropine provided symptomatic relief but it was soon learned that ulcers would not heal unless the acidity was neutralized for long periods of time. This led to the use of antacids like aluminum hydroxide, magnesium hydroxide, and calcium carbonate. Antacids seemed to be very efficacious in the majority of patients and supported the notion that if you get rid of the acid, you will cure the ulcer and the patient. The phrase "no acid, no ulcer" was even coined by Karl Schwartz in 1910 and explained the significant role acid played in ulcer formation.

FROM SURGERY TO MEDICATIONS

In 1943, Lester Dragstedt discovered that vagal stimulation caused hypersecretion of acid in the gastrointestinal tract and that acid hypersecretion was related to ulcer development. This revelation is how surgery became a popular "cure" for peptic ulcers. Performing a vagotomy on a peptic ulcer patient provided symptomatic relief in just over a week. Of course there is always room for improvement, and so different types of surgeries were introduced in order to reduce side effects and complications. Eliminating acid was the acclaimed cure for peptic ulcers at the time and these surgeries did just that. For that reason, surgeries remained the mainstream of treatment for many years until new drugs started to be discovered. With the advent of histamine type-2 receptor antagonists in the 1970's, the mainstay of treatment moved from surgical to pharmaceutical. Proton pump inhibitors were soon after developed and possessed even greater efficacy and greater duration of action than histamine type-2 receptor antagonists.

THE REAL CULPRIT

For centuries, acid was thought to be the cause of peptic ulcers. Due to this thought, that was so widespread, ulcers were managed with antacids to neutralize the acid, surgery to eliminate secretion of acid, and histamine type-2 receptor antagonists and proton pump inhibitors to decrease acid. They were all popular treatments and seemed to be very efficacious. It was not until the 1980's that Helicobacter pylori was identified as major player in peptic ulcer formation. This spirochete shaped bacteria produces enzymes that allow it to survive in acidic environments and molecules that allow it to adhere to the lining of the gastrointestinal tract. H. pylori also produce toxins causing the gastrointestinal tract to react resulting in an inflammatory response. This inflammatory response weakens the mucosal lining and predisposes the patient to ulcer formation.

H. pylori is the most common cause of peptic ulcers. The second most common cause is NSAIDs. This class of drugs decreases prostaglandin production which decreases mucosal blood flow and proliferation and increases mucosal injury. NSAID induced ulcers are usually superficial but can deepen and cause hemorrhaging or even death.

TREATMENT TODAY

Treatment for NSAID induced ulcers is fairly simple. The NSAID being used should be stopped and symptomatic treatment should be given. Antacids, histamine type-2 receptor antagonists, or proton pump inhibitors are common choices to decrease acid secretion and allow the ulcer to heal. Treatment for H. pylori induced ulcers is more in depth. The main goal of treating these types of ulcers is to kill the bacteria and reduce the level of acid to relieve

pain and promote healing. The recommended primary treatment is referred to as triple therapy. It includes a proton pump inhibitor and two antibiotics (usually clarithromycin plus amoxicillin or metronidazole). This treatment is given for 14 days in hopes of killing H. pylori while reducing acid so the ulcer can heal. Another first line treatment option is quadruple therapy. This type of treatment uses a proton pump inhibitor, bismuth subsalicylate or subcitrate, and two antibiotics (usually metronidazole and tetracycline). If the H. pylori is resistant to triple or quadruple therapy and infection persists after 14 days of treatment, salvage therapy may be attempted. Sequential therapy is another second line treatment option but requires further validation for use. Specific doses and durations of treatment are mapped out in the American College of Gastroenterology Guideline on the Management of Helicobacter pylori Infection. One major factor to consider when treating patients is their adherence to their medication regimen. In the treatment of H. pylori induced ulcers, it is very important the patients are able to adhere to the regimen in order to eradicate the bacteria and provide an environment for which the ulcer can heal.

CONCLUSION

The "no acid, no ulcer" theory that was popular for such a lengthy period of time seems to be true to some degree even today. Although H. pylori and NSAIDs are the most common causes of peptic ulcers, they are certainly not the only reasons peptic ulcers develop. Smoking, excessive alcohol consumption, physical or emotional stress, and radiation therapy can all contribute to ulcer formation. The presence of acid does not cause ulcers singlehandedly but it can significantly prolong healing or worsen developing ulcers. It is important to remember that ulcers do not develop from one specific cause. For that very reason, treatments are multifaceted, targeting H. pylori or discontinuing the NSAID as well as decreasing acid in the gastrointestinal tract.

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Liver Disorders:
Part II: Adjusting Medications in Hepatic Dysfunction

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Learning Objectives:
After reading this article and completing the assessment questions, the participant will be able to:

1. Identify scoring systems used to assess the severity of liver disease.
2. Given an actual or simulated case of a patient with liver disease, determine the severity classification.
3. Recognize medications that require dosage adjustment in patients with liver dysfunction and provide dosing recommendations based on the severity of disease.

In the first installment of the liver disorders series we learned how to identify a patient with complications of cirrhosis by looking at a medication profile. In this part we are going to discuss how cirrhosis impacts the clearance of medications and which medications require dosage modifications in this patient population. To begin the discussion let's take a brief trip down memory lane to review a little anatomy, physiology and pharmacokinetic terminology. The liver is a uniquely positioned organ located in between the upper gastrointestinal tract and the general circulation allowing it to act as the body's filter. Regulating the metabolic composition of the blood is one of the main functions of the liver along with hematologic regulation (albumin/clotting protein production) and bile production. All of these functions can be significantly altered depending on the degree of cirrhosis. Unfortunately, unlike in renal disease where the Cockcroft-Gault equation can be used to estimate the degree of renal dyfunction, there is no quantitative measure of liver function and impairment. The best way to estimate the degree of liver dysfunction to date is using the Child-Pugh score, shown in Table 1. The resulting number of points from the Child-Pugh classification can be interpreted as follows; 5 to 6 points indicates class A or mild disease, 7 to 9 points indicates class B or moderate disease and, 10 to 15 points indicates class C or severe disease. Hepatic encephalopathy severity can also be classified by a scoring system known as the West Haven Criteria which can be found in Table 2.

The metabolism of medications (hepatic clearance) is affected in multiple ways in patients with cirrhosis. A decrease in hepatocyte (the main functional cells in the liver) function can alter the ability of the liver to metabolize medications resulting in an increase in medication half-life. One of the enzyme systems frequently discussed with respect to medication metabolism is the cytochrome P450 enzyme system, often abbreviated CYP450.[1-3] Studies have been conducted to determine how various CYP enzymes are affected depending on the degree of liver dysfunction. It appears that certain enzymes are affected to a greater extent even when mild hepatic disease is present. In a model created by Frye and colleagues it is suggested that CYP2C19 is affected in mild hepatic disease with the following enzymes being affected in severe hepatic disease CYP1A2, CYP2D5, CYP2E1.[4] CYP3A4 was not included in this evaluation despite its prominent role in drug metabolism with more that 50% drugs metabolized via this specific enzyme. Additional studies have demonstrated a reduced clearance in medications metabolized via CYP3A4, such as midazolam, nifedipine and everolimus. While the ability of the CYP450 enzyme system to metabolize medications is certainly affected by liver disease, blood flow to the liver is often altered as well. Decreased or altered blood flow to the liver allows medications absorbed from the intestine to bypass the liver and first-pass metabolism. This ultimately increases the bioavailability of the medication if the drug delivered is also exerting the pharmacologic effect or decreases bioavailability if the drug delivered is a prodrug.

In addition to alterations in hepatic clearance, drug distribution is effected by the decreased production of albumin as well as the presence of edema and ascites.[1-3] Medications that are highly protein bound have a much higher free concentration in patients with cirrhosis. Unbound medication has the ability to distribute more widely throughout the body, resulting in an enhanced and possibly toxic pharmacologic effect. In addition, medications that are hydrophilic (water-soluble) will have a larger volume of distribution when patients have edema and ascites present.

The discussion in the previous paragraphs has focused on pharmacokinetic (effects of the body on medications) changes that occur as the result of cirrhosis. Table 3 contains specific medications that are affected to various degrees depending on the severity of liver disease. Dosage recommendations and mechanism

for altered kinetics can also be found in this table. Pharmacodynamic (effects of medications on the body) alterations are also seen in patients with cirrhosis. More specifically a decrease in efficacy is observed with β-adrenoreceptor antagonists (propranolol) and diruetics.[1-3] On the other hand an increased effect is seen with analgesics, anxiolytics and sedatives. As a result of these alterations, dosage adjustments may be required based on response. When using analgesics, anxiolytics and sedatives in patients with liver disease it would be reasonable to start at the lower end of the dosage range and titrate based on response.

In conclusion liver dysfunction affects the metabolism and distribution of many medications. When a patient's medication profile reveals clues that they may have cirrhosis, and a medication addressed in this paper is prescribed, it will be necessary to ensure the appropriate adjustment has been made or give the patient's prescriber a call to clarify or recommend a medication that would be better suited based on the patient's comorbidities.

Table 1: Child-Pugh Classification System for Liver disease[5]

	1 point	2 points	3 points
Serum bilirubin (mg/dL)	< 2	2 to 3	> 3
Serum albumin (g/dL)	> 3.5	2.8 to 3.5	< 2.8
Prothrombin time (seconds > control- assume control of 13)	< 4	4 to 6	> 6
Encephalopathy (grade)	None	1 or 2	3 or 4
Ascites	Absent	Slight	Moderate

Table 2: West Haven Criteria for Hepatic Encephalopathy[6]

Stage	Clinical Signs and Symptoms
Stage 0	No alterations in personality or behavior. No asterixis.
Stage 1	Lack of awareness. Shortened attention span. Impaired addition or subtraction. Sleep disturbances. Mood alterations. Asterixis.
Stage 2	Lethargy/ apathy. Disorientation. Inappropriate behavior. Slurred speech. Obvious asterixis.
Stage 3	Gross disorientation. Bizarre behavior. Semistupor to stupor. Asterixis generally absent.
Stage 4	Coma

Table 3: Suggested dosage adjustments in patients with cirrhosis[2,7-12]

Medication or class	Mechanism of decreased hepatic clearance	Usual dose	Dose in mild cirrhosis	Dose in moderate cirrhosis	Dose in severe cirrhosis
Abacavir (Ziagen®)	Decreased metabolism and protein binding	300 mg twice daily or 600 mg once daily	200 mg twice daily	Not recommended	Not recommended
ACE inhibitors	Decreased conversion of prodrug for benazepril, enalapril, fosinopril, ramipril quinapril	n/a	Use non-prodrug ACE inhibitors (captopril and lisinopril)	Use non-prodrug ACE inhibitors (captopril and lisinopril)	Use non-prodrug ACE inhibitors (captopril and lisinopril)
Alprazolam (Xanax ®)	Decreased CYP3A4 clearance	0.25 to 0.5 mg three times daily	50% of usual daily dose	50% of usual daily dose, use with caution	Not recommended
Anagrelide (Agrylin®)	Decreased metabolism	Initial dose 0.5 mg QID or 1 mg BID	No change in dosage necessary	Initial dose 0.5 mg daily	No data, use with caution
Atazanavir (Reyataz®)	Decreased metabolism and protein binding	400 mg daily OR 300 mg daily + ritonavir 100 mg	No change in dosage necessary, use with caution	300 mg daily, use with caution	Not recommended
Atomoxetine (Strattera®)	Decreased metabolism	40 mg daily	No change in dosage necessary	Decrease dose by 50%	Decrease dose by 75%
Bupropion (Zyban®, WellbutrinXR ®)	Decreased metabolism and protein binding	Initial dose 150 mg daily Max dose 300 mg daily	No dosage adjustment necessary, use with caution	No dosage adjustment necessary, use with caution	Max dose 150 mg every other day
Celecoxib (Celebrex®)	Decreased metabolism and protein binding	200 mg daily or 100 mg BID	No dosage adjustment necessary	Decrease dose by 50%	Not recommended
Darifenacin (Enablex®)	Decreased metabolism and protein binding	Initial dose 7.5 mg daily Max dose 15 mg daily	No dosage adjustment necessary	Max dose 7.5 mg daily	Not recommended
Desloratadine (Clarinex ®)	Decreased metabolism and protein binding	Initial dose 5 mg daily	Initial dose 5 mg every other day	Initial dose 5 mg every other day	Initial dose 5 mg every other day
Esomeprazole (Nexium®)	Decreased metabolism and protein binding	Max 40 mg daily	No dosage adjustment necessary	No dosage adjustment necessary	Max dose 20 mg daily
Eszopiclone (Lunesta®)					Initial dose 1 mg daily
Felodipine (Plendil®)	Decreased first-pass effect	2.5-20 mg daily	Initial dose 2.5 mg daily		
Fluoxetine (Prozac®)	Decreased metabolism	Initial dose 20 mg daily	50% reduction in dose	50% reduction in dose	50% reduction in dose
Fosamprenavir (Lexiva®)	Decreased metabolism	Therapy naïve 1400 mg BID OR 1400 mg daily + ritonavir 100 or 200 mg daily OR 700 mg BID + ritonavir 100 mg BID Protease Inhibitor(PI)-experienced 700 mg BID + ritonavir 100 mg BID	Therapy naïve 700 mg BID PI-experienced 700 mg BID + ritonavir 100 mf daily Use with caution	Therapy naïve 700 mg BID PI-experienced 450 mg BID + ritonavir 100 mg daily	Therapy naïve 350 mg BID PI-experienced 300 mg BID + ritonavir 100 mg daily
Galantamine (Razadyne®)	Decreased metabolism	Max dose 32 mg daily	No dosage adjustment necessary	Max dose 16 mg daily	Not recommended
Letrozole (Femara®)	Decreased metabolism	2.5 mg daily	No dosage adjustment necessary	No dosage adjustment necessary	2.5 mg every other day
Losartan (Cozaar®)	Decreased first-pass effect and protein binding	50 mg daily	Initial dose 25 mg daily	Initial dose 25 mg daily	Initial dose 25 mg daily
Nifedipine (ProcardiaXR®)	Decreased metabolism and protein binding	Initial 30 to 60 mg daily	Initial dose 50% of usual dosing	Initial dose 50% of usual dosing	Initial dose 50% of usual dosing
Nilotinib (Tasigna®)	Decreased metabolism and protein binding	400 mg BID	Newly diagnosed Ph+ CML- Initial dose 200 mg BID,	Newly diagnosed Ph+ CML- Initial dose 200 mg BID, increase to 300 mg	Newly diagnosed Ph+ CML- Initial dose

Medication or class	Mechanism of decreased hepatic clearance	Usual dose	Dose in mild cirrhosis	Dose in moderate cirrhosis	Dose in severe cirrhosis
			increase to 300 mg BID if tolerated Resistant or intolerant Ph+ CML- Initial dose 300 mg BID, increase to 400 mg BID if tolerated	BID if tolerated Resistant or intolerant Ph+ CML- Initial dose 300 mg BID, increase to 400 mg if tolerated	200 mg BID, increase to 300 mg BID if tolerated Resistant or intolerant Ph+ CML- Initial dose 200 mg BID, increase to 300 mg BID and then 400 mg BID if tolerated
Ondansetron (Zofran®)	Decreased first-pass effect, metabolism and protein binding	Dosage regimens vary- generally 4 to 8 mg every 4 to 6 hours (Max 32 mg daily)	No change in dosage necessary	Maximum daily dose 8 mg	Maximum daily dose 8 mg
Paroxetine (Paxil®)	Decreased metabolism and protein binding	Initial dose 20 mg daily	Initial dose 10 mg daily	Initial dose 10 mg daily	Initial dose 10 mg daily
Pilocarpine (Salagen®)	Decreased metabolism	5 mg TID	No dosage adjustment necessary	Initial dose 5 mg twice daily	Not recommended
Rimantadine (Flumadine®)	Decreased metabolism and elimination	100 mg BID	No dosage adjustment necessary	No dosage adjustment necessary	100 mg daily
Sildenafil (Viagra®)	Decreased metabolism and protein binding	Initial dose50 mg as needed	Initial dose 25 mg as needed	Initial dose 25 mg as needed	Not recommended
Solifenacin (Vesicare®)	Decreased metabolism	Initial dose 5 mg daily Max dose 10 mg daily	No dosage adjustment necessary	Max dose 5 mg daily	Not recommended
Vardenafil (Levitra®)	Decreased metabolism and protein binding	Initial dose 10 mg as needed Max dose 20 mg as needed	No dosage adjustment necessary	Initial dose 5 mg as needed Max dose 10 mg as needed	Not recommended
Venlafaxine (Effexor®)	Decreased first pass metabolism and clearance	75 mg daily	No dosage adjustment necessary	Decrease dose by 50%	Decrease dose by 50%, may require additional reduction

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This program is Knowledge Based—acquiring factual knowledge that is based on evidence as accepted in the literature by the healthcare professions.

Continuing Education Quiz

This month's questions are taken from the article on "*Liver Disorders: Part II: Adjusting Medications in Hepatic Dysfunction*". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230-1701. There is no charge for this quiz for MPhA members (non-members $ 10.00). Program release date: February 2, 2011. Program expiration date: June 30, 2012. This program provides for 1.00 contact hour ((0.1 CEU) of continuing education credit. A continuing education certificate will be sent to you within six to eight weeks. ACPE# 0144-0000-11-014-H01P

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

1. The scoring system used to quantitatively assess severity of liver disease is known as which of the following?
   a. Child-Pugh
   b. West Haven
   c. CHADS-2
   d. SOFA score

2. One portion of the quantitative assessment of liver disease severity is evaluation of hepatic encephalopathy (HE). The scale used to evaluate HE is known which of the following?
   a. Child-Pugh
   b. West Haven
   c. CHADS-2
   d. SOFA score

3. Cirrhosis can have which of the following effects on the pharmacokinetics of medications?
   a. Decreased plasma protein binding
   b. Decrease first pass metabolism
   c. Decreased clearance
   d. All of the above

4. Which of the following variables can have the greatest effects on hepatic first pass metabolism?
   a. Altered blood flow to the liver
   b. Hepatocyte damage
   c. Protein binding
   d. Hydrophilicity of the medication

5. All CYP450 enzymes are affected to the same degree by cirrhosis severity (true or false).
   a. True
   b. False

6. It is well recognized that medications administered to patients with cirrhosis have altered pharmacokinetic properties. Which of the following medication classes is known to show altered pharmacodynamic properties in patients with cirrhosis?
   a. ACE inhibitors
   b. ARBs
   c. B-blockers
   d. Calcium channel blockers

The following case should be used to answer questions 7-10. RL is a 63 year old Caucasian male with PMH significant for osteoarthritis, alcohol abuse, cirrhosis, SBP and variceal hemorrhage. His most recent labs show the following results.

- Sodium 138, Potassium 4, Chloride 102, Bicarbonate 24, Blood urea nitrogen 18, Serum creatinine 0.8, Glucose 95
- WBC 5, Hemoglobin 13, Hematocrit 39, Platelets 132
- AST 45, ALT 45, Bilirubin 2.8, Albumin 3.3, PT/INR 18/2.1

On physical exam he is noted to have a moderate amount of ascites and no encephalopathy. His current medications include the following; ciprofloxacin 750 mg PO once weekly, furosemide 40 mg PO daily, spironolactone 100 mg PO daily, propranolol 20 mg PO every 12 hours, lactulose 10 grams every 4 to 6 hours (titrate to 2-3 soft BMS daily), and acetaminophen 500 mg every 6 hours PRN pain. At his last doctor's visit RL's chief complaints included increased pain in his knees not relieved by acetaminophen and increasing depression about his cirrhosis. He brings 2 new prescriptions to your pharmacy to be filled for celicoxib 200 mg PO daily and paroxetine 20 mg PO daily.

7. What is RL's Child-Pugh Score?
   a. 6
   b. 7
   c. 8
   d. 9

8. What dose would you recommend celicoxib be initiated at?
   a. 200 mg PO daily, no dosage adjustment is necessary
   b. 100 mg PO BID
   c. 100 mg PO daily
   d. Celicoxib should not be used in this patient

9. What dose would you recommend paroxetine be initiated at?
   a. Paroxetine should not be used in this patient
   b. 10 mg PO every other day
   c. 10 mg PO daily
   d. 20 mg PO daily, no dosage adjustment is necessary

10. Which medication in RL's medication list may require higher doses to achieve the desired effect due to a altered pharmacodynamic effect?
    a. Ciprofloxacin
    b. Acetaminophen
    c. Lactulose
    d. Furosemide

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President's Message

Being Part of the Team…

Why do people belong to associations? The Association Executive's Little Black Book says "it is out of necessity to belong".

I started out that way when I graduated from the University of Maryland, Baltimore in 1992. I did not have extra time to be active but, I went to midyear meetings in Columbia and annual meetings in Ocean City. Before I knew it, I was on the Board of Trustees.

Attending the midyear meeting or annual convention is a great way to start the process. Networking at meetings is a way to get new ideas and maybe find your next great job. Taking small steps can help improve personal and professional lives.

Pharmacists are busy like everybody else but, we need to be involved so we can steer our profession and not have it driven for us by other groups. Each of us can have a big impact with a small amount of time and dedication. Membership, committees and attendance at events are some the many ways you can get involved. *Your first step is to e-mail me.*

We have expanded our staff with the addition of Margaret (Peggy) Funk. She comes to us from UMB Pharmacy School and will bring many new ideas to the table.

I have some goals for the year.

- more timely information distributed electronically.
- determine how MPhA can best serve the needs of all pharmacists: staff, managers, administrators and owners.
- lobbying in Annapolis, member benefits, quality programming can help all of us.

I'd like more ideas from you.

Here is another easy step for you, if you are not a friend of MPhA on Facebook, *like us.* Important state pharmacy news, pictures and convention information are just a few things you will find.

Thank you for being part of the team.

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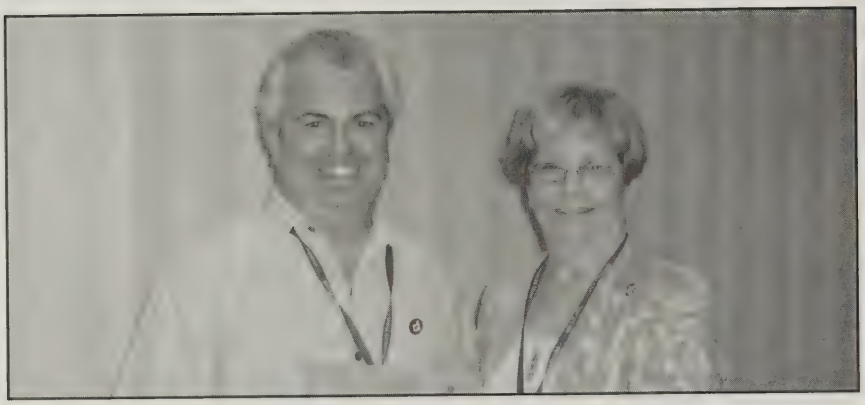

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"Medication Therapy Management (MTM) Light" Series: Practical Guidance for Maryland Pharmacists to Develop and Implement MTM Services

In a continued effort to meet Maryland pharmacists' needs, the Professional Development Committee has initiated an MTM light series to assist pharmacists incorporating MTM services into current pharmacy practice. With an introductory article (1) in the June-July-August 2010 issue of the journal, there will be a series of articles highlighting a variety of topics, including: (2) collaborating with physicians; pharmacist-physician relationships, (3) conducting a SWOT analysis; obtaining pharmacist's credentials and National Provider Identification (NPI) for clinical services, (4) documenting, monitoring and tracking patient care, and (5) obtaining compensation/ reimbursement for clinical/cognitive services. Look for these articles in current and future issues of the journal.

Article 4

Establishing a Medication Therapy Management (MTM) Practice: Documenting and Monitoring Patient Care

Amy Nathanson, PharmD and Cherokee Layson-Wolf, PharmD, CGP

Documentation of medication therapy management (MTM) is important to validate the specialty services provided by pharmacists. Through documentation of services, pharmacists can involve patients in their therapy management, communicate with other health care providers, and bill for services provided. Creation of patient charts after an MTM review documents a thorough evaluation of the patient's medications, records medication related problems, and allows for appropriate follow up. This article summarizes essential documentation requirements to support an MTM service, reviews the purpose of documentation, and discusses methods to maintain records.

What type of documentation is needed?

According to the Core Elements of MTM, there are four documents that should be completed for each comprehensive medication review (CMR). Each document has its own distinct purpose and is focused toward either the patient or the provider. These documents include:

1. *Patient History and Medication Therapy Review (MTR)*

   This document is a general overview of the patient that also contains information related to the patient's past medical history, current and past medications, adverse drug reactions and allergies, family and social histories, primary reason for encounter or chief complaint, date and pharmacist identification. When available, objective data should be incorporated, such as pertinent laboratory data, blood pressure, pulse, and weight. Additional information to collect include the patient's own goals of treatment, and a discussion of their values and preferences related to their therapy. This information can help generate items for the medication action plan (MAP) discussed below.

2. Personal Medication Record (PMR)

The PMR document is given to the patient and includes a complete list of all current medications; including prescription, over-the-counter and supplements. In addition to the names of the medications, other information that should be included are dose, indication, directions or time of administration, comments/additional information, physician and pharmacist contact information.

3. *Medication Action Plan (MAP)*

This document is also to be given to the patient as a concrete explanation of the visit findings and steps for the patient to take after s/he leaves the pharmacy. The MAP describes the medication related problems identified at the visit and establishes a plan to remedy these findings, as well as follow-up. The goal of the medication action plan is to empower the patient to take action to manage their medications and potential problems. Medication related problems may include inappropriate dose, inappropriate drug, untreated indication, adverse event, drug interactions, or ineffective use of medication/ adherence/technique. Patients can take action to modify a technique or behavior, however, they may need to have a discussion with their physician to determine whether certain medications are still required or new therapy should be added.

Assessment and Follow-up

4. *SOAP (Subjective, Objective, Assessment, Plan) Note*

After discussing your findings with the patient, it is important to summarize the visit and findings with a SOAP note. This document incorporates the data gathered from the patient history in the subjective section and any labs or measurements in the objective section. It also includes the pharmacist's assessment of any medication related problem(s) and establishes a plan to remedy the problem(s). The plan would include monitoring and follow-up. This more formal document can be used to communicate with the patient's primary care physician or other providers.

5. *Provider communication and follow-up*

After finalizing the SOAP note, it is necessary to send a copy to the patient's physician. This can be done by fax or mail. It may be helpful to send a cover letter explaining what an MTM service entails. When communicating with other health care practitioners it is also good practice to follow up after sending a fax request for lab work with a phone call. Typically this will yield more prompt delivery of results.

Recreating the wheel? Use a lifeline!

So do you have to create all these documents yourself? Not necessarily. Taking a few moments to generate standard forms for the MTR, PMR, MAP and SOAP note will save time in the long run. Having electronic templates to enter information will make the document readable, but also allow for easy maintenance of files. The forms can be formatted with site specific information and then tailored to each patient. There are resources available with sample forms to use, or there are programs that may have standardized forms to customize. Examples of these forms can be found at the following link: http://www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=15496&TEMPLATE=/CM/ContentDisplay.cfm

Paper or digital? That is the question!

Documentation can be completed in paper format or electronically. This is up to the discretion of the pharmacist. The advantages of paper charts include the forms are readily available, easily portable, and are low cost. One disadvantage is the large amount of physical space needed for secured storage of records. On the other hand, electronic charts do not take up physical storage space but rather virtual storage space which needs to be protected. Additional staff training may be necessary on these computer systems.

Some companies have created MTM programs that pharmacies can contract with and receive compensation for their services. Often, these programs have their own documentation systems. Some of these programs are Outcomes Pharmaceutical Health Care, Mirixa Corporation, PharmD Solutions, LLC and Medication Management Systems, Inc. Compensation will be discussed further in a subsequent article.

These documentation systems also enable for easier tracking of patients who have received the service and can assist in determining when patients may be due for follow-up. They can tag a patient for an annual review. If choosing to use paper documentation, then a separate calendar system may be created for follow-up and tracking purposes. This will optimize encounters with participating patients and keep track of visits.

Why this is important?

Documentation of services provided to patients can be time consuming but can also demonstrate the benefit to patients in your practice. In addition, documentation helps track successes as well as identify when more communication needs to occur. Having physicians see more communications regarding MTM can help them realize the benefit of this service and may even help them encourage or refer patients to speak with their pharmacists for assistance.

It does take time to become familiar with these documentation components of MTM, but with more MTM services provided, you will generate a routine to maximize your time with the patient, decrease documentation time, and ease communication with physicians.

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For questions regarding MTM opportunities or suggestions, please contact MPhA Professional Development Committee Co-chairs Kristen M. Fink, PharmD, BCPS, CDE, Clinical Pharmacy Specialist, Kaiser Permanente and Fink's Pharmacy at fink462@hotmail.com or Hoai-An Truong, PharmD, MPH, Assistant Director of Experiential Learning at University of Maryland School of Pharmacy, and MTM Pharmacist at Mercy Health Clinic, Primary Care Coalition of Montgomery County, at htruong@rx.umaryland.edu.

Key Findings and Results of the Appointment Based Model

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John Shilan, Pharm. D. Candidate 2011, Virginia Commonwealth University

Medication non-adherence is a serious problem in the United States that is severely increasing healthcare costs and decreasing patient care. Pharmacists are in a unique position to help. They have the ability and knowledge to implement programs as part of their daily practice to ensure that patients are adherent to their medications. As the medication experts, pharmacists should lead the way to improving medication adherence and providing optimal patient care.

The Appointment Based Model (ABM) is a program that was designed by a pharmacist in Long Beach, California in 1995, and further developed by the National Alliance of State Pharmacy Associations (NASPA). It is a turnkey system that allows you to implement a synchronized, appointment based model in your pharmacy easily and quickly and does not require any integration or modification of your pharmacy management system. By synchronizing multiple, chronic prescriptions for your patients, you will improve patient outcomes, such as improved medication persistency and adherence rates, and improve the efficiency of your practice through decreased daily phone calls in the pharmacy, improve inventory control and the potential to increase prescription volume.

Two recent studies (NASPA ABM Pilot[i] and L&S Pharmacy[ii]) provide evidence on the value of the appointment based model and patient centric care. Some **key** findings from the two studies were that:

- 57% of the non-persistent patients became persistent after 12 months in the ABM
- The percentage of persistent refills in the non-persistent patients increased from 59% prior to the ABM to 76% after implementation
- Of the patients in the persistent group, 90% continued to remain persistent throughout the entire twelve months of the study
- There was a 30% increase in the number of prescriptions dispensed in the post-intervention subgroup (L&S Pharmacy Study)

Pharmacists who have piloted the ABM have positive feedback on the model. They say that, "The program has given us more control over our workflow and better efficiency. It has also allowed us to be more aware of our patients' total healthcare picture. ABM puts us in a consultative role with our patients—asking questions, making recommendations. We're in a position with our ABM patients to know if they are taking too much or too little of their medications. We can now *catch and counsel*!" In addition, the impact that it has had on their practice from an operation standpoint has been tremendously beneficial. Most importantly, pharmacists have said that "… [It] keeps us in touch with our patients. By regularly reviewing their records, we can spot potential medication or compliance issues and address them before they become problems. That results in improved health and money savings for our patients."

Patients may also see a wide variety of benefits beginning with increased medication adherence, fewer phone calls and trips to the pharmacy, increased understanding of their medication therapy, and an enhanced relationship with their pharmacist and other members of their health care team.

For more information and implementation materials please visit: http://www.naspa.us/grants/abm.html

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Rx AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community

CAN I GET SUED FOR THAT?

One of the questions that I get asked a lot is, "Can I get sued for that?" Unfortunately in today's world, I have to answer yes; almost anyone can sue for almost any reason. While there are rules against filing frivolous lawsuits, the filing has to be pretty egregious to be considered frivolous. There are two better questions that get to the heart of what pharmacists really want to know—Do I have exposure for that activity and do I have coverage for it?

Since the bar is pretty low for the filing of a lawsuit, it is almost a given that you can be sued for any activity. However, that doesn't reflect your exposure in that case. Filing a suit is quite different from winning a suit. The plaintiff will still have to prove the four elements of negligence in order to win their case. Let's use pharmacist-administered vaccinations as our example. An analysis and evaluation of the pharmacist's duties and possible breaches of those duties is the first step. Was the protocol followed, was the patient a proper recipient under the protocol, was the proper vaccine given, was it given properly, was the patient given proper information about the risks and benefits of the vaccine? If the answer to all of these questions is yes, then the pharmacist's exposure is low. If not, then additional analysis is needed to see if the breach (or breaches) was the direct cause of the patient's injury. For example, the patient was allergic to eggs, but received the vaccine and suffered an allergic reaction. If this were true, then the pharmacist's exposure is higher.

For any new service, the pharmacist should consider what duties are required for them to provide the service, the possible ways that those duties could be breached, and the possible injuries that could result from that breach. In this way, the pharmacist can evaluate their exposure for providing any new service. As you can see, this is more in depth than merely asking if you can be sued if you administer vaccines.

The second important question is whether there is insurance coverage for the activity in question. Insurance policies typically provide two types of coverage; loss coverage and defense coverage. Loss coverage is the portion of the policy that

covers the damages exposure that we have already discussed. This is obviously very important to have for any activity that a pharmacist performs. Equally important is the defense coverage. This is the portion of the policy that pays for defense attorneys, expert witnesses, court reporter fees, etc. Defense coverage is available in two forms. In one version, the defense costs are included in the loss coverage limit. In this version, if $50,000 is spent on defense costs, then only $950,000 of a $1 million limit is left to pay a loss. This becomes very important in a case that is long and expensive to defend. In the other version, the defense coverage is separate from the loss coverage and doesn't erode the loss limits. In either case, if the loss is covered, the defense coverage provides for the defense of the suit, no matter how frivolous or low the exposure might be. Because of the high cost of legal services, the defense coverage can be an important asset for any pharmacist to have. Even defending a frivolous suit could cost thousands of dollars.

Can a pharmacist be sued for a given activity? The answer is almost certainly yes. But that should not stop a pharmacist from providing inventive, progressive patient care. A more in-depth analysis of the true exposure is required along with verification of insurance coverage for that exposure. There may be activities that are determined to be too risky, but that shouldn't stop pharmacists from continually striving to provide the best possible care for their patients.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Insulin – Then and Now

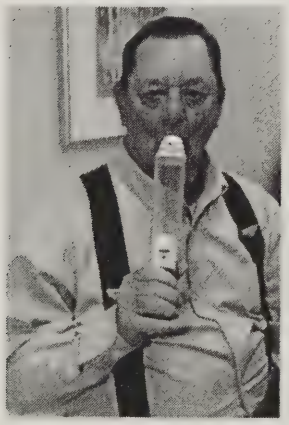
By Minh Nguyen, Pharm.D . Candidate

UMB, School of Pharmacy

It is a common scene—a patient walks into your pharmacy to fill their insulin prescription to manage their diabetes or to treat their pet. A walk over to the refrigerator yields no shortage of insulin—with a wide variety to choose from, it might feel like staring at different cuts of beef in the meat department of your local supermarket. With the prevalence running rampant at 25.8 million or 8.3% of the US population, another 79 million classified as prediabetic, and an incidence of 1.9 million, diabetes show no signs of slowdown. One has to wonder what society did before the discovery of insulin.

Although first described by a German medical student Paul Langerhans in 1869 with his discovery of "islet of Langerhans" cells, it was not until 1921 that scientist Dr. Frederick Banting and medical student Charles Best discovered the role of insulin. A year later, they tested bovine insulin extract in humans—successfully treating diabetes. Before th en, diabetics were treated with a strict diet. In 1923, the Nobel Prize was awarded for the discovery of insulin and Eli Lilly began to purify and produce commercial quantities of bovine insulin. Since then, various types of insulin have been derived and marketed; however, all with the same painful and inconvenient route of subcutaneous administration.

Diabetic patients do SQ injections of insulin about 3-4 times a day, and they complain it about 3-4 times a day. So intuitively, when a diabetic patient is asked, "What is worse than multiple daily SQ injections?" It is safe to assume nothing much. As it turns out, it is not safe to assume nothing, because the answer is Exubera. What is Exubera you might ask—Exubera is the first inhalable insulin product developed and marketed by Pfizer in 2006. How is inhalable Exubera worse than SQ insulin? Let diabetic patient, Daniel Barrow illustrate. Mr. Barrow clearly demonstrates that the cost of being cumbersome and inconvenient does not overcome pain for some. Size was a major complaint among the less than 1% of adopters, along with complicated dosing, due to non-linear relationship with injectable insulin and lung function health issues. Insurance companies were not willing to cover the extra cost of Exubera, $5 per day compared to $2-3 per day of injectable insulin and additional lung function test. Citing poor sales drifting around $12 million annually whereas predicted sales were estimated to be $2 billion, Pfizer decided to discontinue Exubera in 2007. At a total cost of $2.8 billion, this is one of the most stunning failures in history—worthy of sinking 16 Titanics (adjusted for inflation 2011). Avoiding the wake left by Pfizer's sunken cruise ships, Eli Lilly and Novo Nordisk both abounded all development of their inhalable insulin formulations. It is 2011, where does this leave the development of insulin?



Startup biotechnology company, MannKind continued development on Afrezza, their inhalable insulin formulation that they started development in 2001. MannKind felt it was their little engine that could—that it could escape the vortex created by Pfizer. To escape, Afrezza is very portable and convenient, has faster onset and peak compared to Exubera, and cost will be 10-20% over traditional injectable therapies. January of 2011, the FDA failed to approve Afrezza, requesting further trials be conducted.

MannKind expects the trials will be complete by the end of 2012. With the latest knock out come new challengers. Meet Oral-Lyn, an oral insulin spray formulation by Generex Biotechnology. FDA granted Oral-Lyn to enter Phase III clinical trials and placed it under investigational new drug treatment. Phase III reports released in 2009 "show positive result," but no news from Generex since then. The pharmaceutical industry, like the movie industry is not short on hype and promises to promote their next blockbuster. Drug companies are currently promising intranasal, and transdermal delivery of insulin via iontophoriesis and ultrasound. However, the biggest promise is the elusive unicorn—oral insulin formulation. The struggle in developing an oral formulation of insulin is that, identical to protein

and peptide drugs, insulin is degraded by proteolytic enzymes in the GI tract. Like detecting the Higgs Boson particle at the Large Hadron Collider, currently, four companies, Oramed Pharmaceuticals, Biocon, Apollo Life Sciences, and Emisphere Technologies with Novo Norkdisk are claiming they may have viable oral insulin products which are undergoing various phases of clinical trials. Should insulin users celebrate? Don't hold your syringe plunger just yet! Promises of oral insulin have been made for the last decade with nothing to show for but vapor and abdominal needle marks. With global insulin sales at $15.4 billion in 2010—pharmaceutical, biotechnology, and drug delivery companies maybe in a rat race to get their share of the cake, or cheese. It is still 2011, what should we expected?

A question with a more concrete answer is, "what should we not expect?" Do not expect any break thought insulin products within the next two years. Drugs currently in clinical trials will still be a few years away at the earliest—if they manage to make it to market. In the meantime, diabetic patient will have to *stick* with what they know.

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Continuing Education...

Liver disorders: Part III: Acetaminophen Associated Hepatotoxicity

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Acetaminophen (APAP) overdose has long been known to cause hepatotoxicity that can result in liver failure and death. In the United States, intentional or unintentional overdose with acetaminophen is the leading cause of acute liver failure (ALF) in patients referred for liver transplantation.[1] Readily accessible due to it's OTC status, acetaminophen is reported to have been responsible for 100,000 calls to poison centers annually for potential APAP overdose and in 2005 was the reason for more than 70,000 hospital visits and 300 deaths.[2,3] In addition to its availability as a single agent product, APAP is available in combination with opioids, other analgesics, sedatives, decongestants, and antihistamines. In general acetaminophen toxicity is associated with total daily doses > 4 grams and can occur with a single overdose or large/frequent therapeutic doses.

Acetaminophen is not directly hepatotoxic and the majority of the parent compound is metabolized via glucuronidation and sulfation to nontoxic metabolites which are subsequently eliminated in the urine.[2,3] A small amount of acetaminophen (~5 to 15%) is metabolized by CYP2E1 to N-acetyl-p-benzoquinone imine (NAPQI). NAPQI is extremely hepatotoxic but is usually detoxified quickly by glutathione and the resultant compounds are also eliminated in the urine. In an overdose scenario the sulfation pathway becomes saturated and additional acetaminophen undergoes oxidation by CYP2E1 resulting in large quantities of NAPQI. Glutathione stores become depleted, and NAPQI causes ALF by binding to hepatocytes and causing cell death or hepatocellular necrosis. It is estimated that for hepatic damage to ensue, glutathione stores must be depleted to < 30% of normal levels. Four stages have been defined in the progression of acetaminophen poising, including; stage I (preclinical toxic effects), stage II (hepatic injury), stage III (hepatic failure) and stage IV (recovery).

The four stages in general correlate with time from ingestion and are defined by symptomatology and laboratory findings. During stage I (1 to 24 hours) no laboratory abnormalities are present however, nonspecific symptoms including; nausea and vomiting, may be present.[1,3] Stage II generally occurs within 24 hours after ingestion but can occur up to 48 hours and marks the start of hepaticdamage. The most sensitive laboratory abnormality associated with hepatocyte damage secondary to acetaminophen toxicity are elevations in aspartate aminotransferase (AST), an aminotransferase enzyme, to > 1000 international units/ L. Further elevations in aminotrasferases (both ALT and AST) are seen between 72 and 96 hours after ingestion (stage III) along with abnormalities in additional laboratory values including; elevations in total bilirubin, conjugated bilirubin, PT/INR and decreased albumin. Alterations in bilirubin, PT/INR and albumin values are indicative of the degree of hepatic damage and mortality predictions associated with the overdose.

The spectrum of severity of ALF caused by acetaminophen is vast and can range from full recovery to death. The stages of acetaminophen toxicity defined earlier are used to identify treatment options as well as to predict morbidity and mortality for the particular poisoning. Patients who receive treatment during the preclinical stage are likely to recover fully, whereas those patients who are treated after hepatic injury has occurred have a course that is less easy to predict. Finally mortality is highest in patients with fulminant hepatic failure with a rate of between 20 and 40%. Generally death occurs between 3 and 5 days after the ingestion and can be attributed to multiorgan failure, hemorrhage, acute respiratory distress syndrome, sepsis and cerebral edema.[3] Laboratory

predictors of poor outcome include metabolic acidosis (pH<7.3), coagulopathy (PT>100), renal failure (SCr >3 mg) and encephalopathy. Patients who survive stage III progress to stage IV where the remarkable ability of the liver to regenerate is showcased. Laboratory values generally return to normal within 5 to 7 days and acetaminophen poisoning does not cause chronic hepatic impairment.

In addition to the laboratory values mentioned, an APAP level is imperative for determining risk for hepatic injury associated with the ingestion. The timing of ingestion is also pertinent although not always easily obtainable depending on the situation. These two key pieces of information are used in conjunction with the Rumack-Matthew nomogram to determine the best treatment course for each individual patient. The Rumack-Matthew nomogram was published in 1975 and was developed to identify the risk of hepatic injury using time of ingestion and plasma APAP concentration.[3] The Rumack-Matthew nomogram is depicted in Figure 1 and displays the time since ingestion on the x-axis with the plasma acetaminophen concentration on the y-axis. Note the timing of the acetaminophen concentration should be between 4 and 24 hours after the time of ingestion to use the nomogram. If an individual patient point is above the line the likelyhood of hepatic injury is high and antidote therapy with N-acetylcysteine is indicated despite signs or symptoms of hepatic injury. The nomogram cannot be used for patients in which the ingestion time is not known or with repeated supratherapeutic ingestion. If the time of ingestion is not able to be identified the recommendation is to evaluate AST. If AST is elevated, regardless of APAP concentration, antidote therapy is indicated. Need for antidote therapy in repeated supratherapeutic ingestion is more difficult to determine.

Treatment options in acetaminophen overdose include decreasing gastric absorption, supportive care and antidote therapy. Decreasing gastric absorption of acetaminophen is indicated if a patient presents early, usually within 4 hours after ingestion. Activated charcoal can be administered tothese patients and has been shown to decrease APAP concentrations.[3] Charcoal should be administered to adults as a onetime dose of 50 to 100 grams or in children 1 gram/kg. There are relatively few contraindications to charcoal administration other than altered mental status with concerns for aspiration; however this can frequently be overcome by placing an NG tube and administering the charcoal via this mechanism. Supportive care measures are generally focused around controlling nausea and vomiting, although airway protection will be important in patients presenting with altered mental status. In patients with fulminate hepatic failure hypoglycemia can occur as a result of decreased gluconeogenesis and may require use of dextrose preparations. Finally in patients with coagulopathy fresh frozen plasma (FFP) can be considered relative to PT elevations and bleeding risk.

The final treatment option for treatment in patients with acute APAP overdose is the antidote, NAC. NAC has multiple mechanisms for decreasing the morbidity and mortality associated with APAP overdose. NAC serves as a precursor to glutathione increasing availability to decrease the formation of NAPQI.[3] NAC is most effective if administered within 8 hours from the time of ingestion but is frequently used beyond the time point and is still effective in decreasing the amount of hepatic damage. After the 8 hour time period it is likely that the mechanism of NAC in preventing additional hepatic damage lies in its ability to reverse NAPQI oxidation. Additional reports have indicated that with increased time from ingestion NAC may effective in preventing multiorgan failure with a proposed mechanism of increasing oxygen delivery and enhancing organ utilization of oxygen.

NAC is available as an oral (10% and 20% solution) and intravenous (IV) solution (200 mg/mL). To date there are no studies proving that one therapy is better than the other and often the choice is made based on tolerability. Oral therapy, while more convenient, is not practical in patients with altered mental status or patients experiencing nausea and vomiting. In addition, the oral solution has an unpleasant smell and taste making it difficult for some patients to tolerate. It may be necessary to use IV NAC if patients are unable to palate the oral solution. The most common ADE with the IV product is anaphylactic reactions, including; rash, pruritus, angioedema, bronchospasm, tachycardia and hypotension. Dosing is slightly different for the oral and IV products. The oral solution should be given as a onetime loading dose 140 mg/kg with subsequent maintenance dosing 70 mg/kg every 4 hours for a total of 17 doses (72 hours). The IV solution is administered in series of 3 doses administered over a total of 20

hours. The loading dose is 150 mg/kg administered over 15 minutes to 1 hour. It is followed by the second dose 12.5 mg/kg administered over 4 hours and the third dose 6.25 mg/kg over the remaining 16 hours.

Appropriate monitoring for patients receiving oral or IV NAC includes aminotransferase enzymes (AST and ALT) in addition to APAP concentration. After 20 hours of NAC administration patients may still have significantly elevated AST and ALT levels. In these circumstances it may be reasonable to continue with a fourth dose 6.25 mg/kg for an additional 16 hours and a poison center would be able to provide further recommendations with respect to duration.

In summary, acetaminophen when used inappropriately continues to be a significant cause of hepatic injury. Particularly with the number of combination products containing acetaminophen it is possible for patients to take too much acetaminophen without realizing it. This is a pertinent area for community pharmacists to intervene and educate patients. Finally, time is liver. Time from ingestion will determine therapeutic course

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Dr. Lauren Hynicka, Pharm.D., BCPS has no financial disclosures to report.

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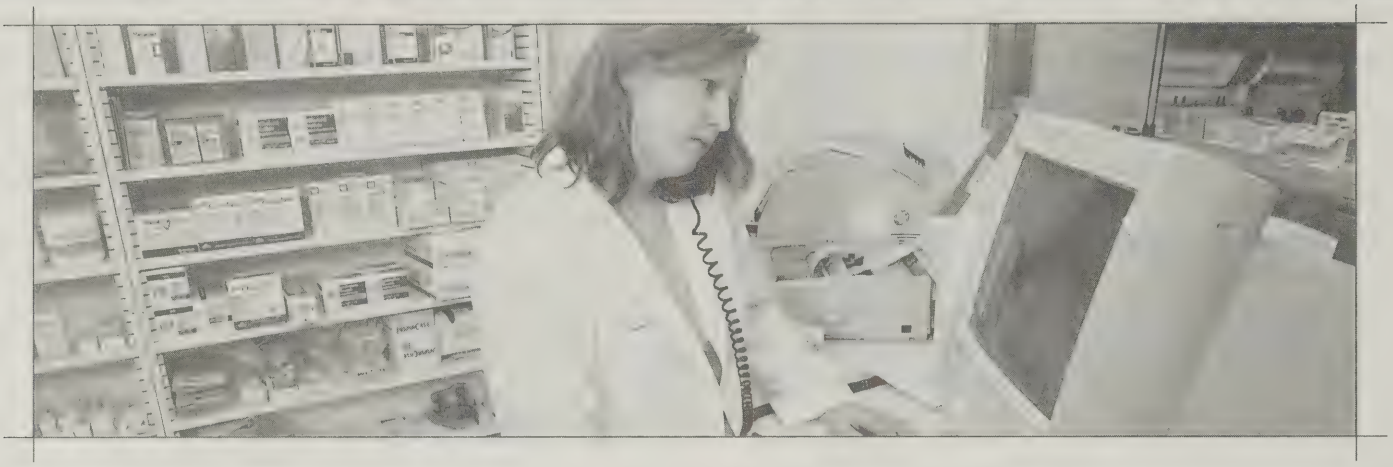

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Continuing Education Quiz

This month's questions are taken from the article on "*Liver Disorders: Part III: Acetaminophen Associated Hepatotoxicity*". Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230-1701. There is no charge for this quiz for MPhA members (non-members $ 10.00). Program release date: August 15, 2011. Program expiration date: October 31, 2012. This program provides for 1.00 contact hour ((0.1 CEU) of continuing education credit. A continuing education certificate will be sent to you within six to eight weeks. ACPE# 0144-0000-11-068-H01-P

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The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

1. Which of the following is the hepatotoxic metabolite of acetaminophen?
   a. N-acetylcysteine (NAC)
   b. N-acetyl-p-benzoquinone imine (NAPQI)*
   c. ACETAMINOPHEN
   d. CYP2E1

2. Large quantities of acetaminophen's hepatotoxic metabolite are able to accumulate due to depletion of which of the following compounds?
   a. Creatinine
   b. Glucose
   c. Bilirubin
   d. Glutathione*

3. What laboratory value that is most likely to be elevated first inacute acetaminophen overdose?
   a. ALT
   b. AST*
   c. PT/INR
   d. Bilirubin

4. Generally laboratory abnormalities are resolved after an acute overdose within how many hours/days?
   a. 24 to 72 hours
   b. 2 to 5 days
   c. 5 to 7 days*
   d. 7 to 10 days

5. Which medication regimen can be used to decrease the gastric absorption of acetaminophen during an overdose?
   a. NAC
   b. Kayexylate
   c. Charcoal*
   d. Glutathione

6. The Rumack-Matthew nomogram predicts which of the following?
   a. risk of hepatic injury*
   b. time it will take for lab value to return to normal
   c. dose of NAC needed to treat acute acetaminophen overdose
   d. length of treatment with NAC

7. The Rumack-Matthew nomogram should only be used for which of the following scenarios?
   a. A 65 year old male found down by a neighbor with an empty bottle of acetaminophen beside him.
   b. A 45 year old female presenting with N/V who has been taking 6 grams of acetaminophen daily for pain over the last 2 weeks.
   c. A 53 year old female brought to the ER by her daughter with altered mental status. The daughter noted the medicine cabinet was open and the acetaminophen bottle was empty in her mother's home.
   d. A 68 year old male presenting to the ER reporting to have taken 20 tablets of acetaminophen 650 mg 3 hours ago.*

8. Which of the following is a correct NAC regimen for the treatment of acetaminophen overdose?
   a. 150 mg/kg PO x 1 dose, 70 mg/kg PO every 4 hours x 17 doses
   b. 140 mg/kg PO x 1 dose, 70 mg/kg PO every 6 hours x 72 hours
   c. 150 mg/kg IV x 1 dose, 12.5 mg/kg IV over 4 hours, 6.25 mg/kg IV over 16 hours*
   d. 140 mg/kg IV x 1 dose, 12.5 mg/kg IV over 4 hours, 6.25 mg/kg IV over 20 hours

9. NAC is most effective if administered within how many hours post ingestion?
   a. 1-2 hours
   b. 4 hours
   c. 8 hours*
   d. 24 hours

10. What is the recommended maximum daily dose of acetaminophen that should be consumed in 24 hours?
   a. 2 grams
   b. 4 grams*
   c. 6 grams
   d. 8 grams

Maryland Pharmacist

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CONTINUING EDUCATION: MANAGEMENT OF
HEAD LICE INFESTATION

Neil Leikach
President

Have you ever been delayed at an airport because of Mother Nature? It happened to me after the Baltimore Ravens home opener. So I took the opportunity to sit down and write the president's message for the *Maryland Pharmacist* journal.

You have seen commercials for the credit card that states membership has its privileges. If it works for a piece of plastic, it should definitely work for a state association like ours. For the small price of dues, you as a pharmacist or pharmacy technician can get informative continuing educations credits either on paper throughout the year or live CE's at least twice a year. This would be enough to get the credits — including the live, medication safety, and immunization CEs—needed to renew your Maryland license. Also MPhA will soon be adding the membership benefit of online CEs.

Are you getting up-to-date pharmacy information weekly via the *Monday Message*? If so, then thank you for sharing your e-mail address! If not, e-mail or call the office at 410.727.0746 to be added so that you can get the latest Association news every Monday. Just this month, we began offering the monthly newsletter, *Pharmacy News*, electronically so that we can bring you important and timely information as well as give you links to additional resources. Visit our website—marylandpharmacist.org—for a listing of all of the membership benefits including discounts for local and national vendors.

You may have some new ideas about what's in it for you when you renew your membership and, therefore, I am asking you to send in your renewal form since you are thinking about it. We know other pharmacists that may or may not belong to our association. Please ask your fellow pharmacists if they are members of the Maryland Pharmacists Association. If they are, thank them and remind them it is time to renew. If they are not, encourage them to check out the website and tell them why you are a loyal member. I also welcome your colleagues and you to email me at leikach@verizon.net and as I mentioned before, I'd love to hear from you. I have gotten a few e-mails already and I enjoy getting feedback from the members. Thank you and I hope you enjoy this newly updated edition of the *Maryland Pharmacist*.

Have a great holiday season!

Warm regards,
Neil Leikach, *President*
leikach@verizon.net

The Mission

PROMOTING excellence in pharmacy practice
STRENGHTENING the profession of pharmacy
ADVOCATING for all Maryland pharmacists

Maryland Pharmacist

FALL 2011

Advertiser's Index

We welcome your feedback and ideas for future articles for Maryland Pharmacists. Send your suggestions to Peggy Funk, Maryland Pharmacists Association, 1800 Washington Blvd., Ste. 333, Baltimore, MD 21230, or email peggy.funk@mdpha.com, or call 410.727.0746

Practical Guidance for Maryland Pharmacists to Develop and Implement MTM Services

In a continued effort to meet Maryland pharmacists' needs, the Professional Development Committee has initiated an MTM light series to assist pharmacists incorporating MTM services into current pharmacy practice. Starting with an introductory article in the Summer 2010 issue of the journal, there has been a series of articles highlighting a variety of topics, including:

- collaborating with physicians; pharmacist-physician relationships;
- conducting a SWOT analysis; obtaining pharmacist's credentials and National Provider Identification (NPI) for clinical services;
- documenting, monitoring and tracking patient care; and
- obtaining compensation/ reimbursement for clinical/ cognitive services.

With this article as the last one in the series, please look for the previous four articles in recent issues of the journal and suggest ideas for other potential series or topics.

ARTICLE 5

Establishing a Medication Therapy Management (MTM) Practice: Obtaining Compensation for Clinical Services

By Christine Lee-Wilson, PharmD and Ashley E. McCabe, PharmD

At the culmination of this *Medication Therapy Management (MTM) Light* series, it is anticipated that these articles have provided insights and perspectives on MTM services to help invigorate and bring innovation to your practice. As with all innovations, MTM is only sustainable when it can support itself. This brings the final topic to light. The once remote thought of pharmacists being compensated for clinical services is no longer just that. Reimbursement for clinical services is achievable; however, it is neither simple nor entirely explicit. The purpose of this article is to offer guidance for pharmacists providing these services toward achieving a sustainable MTM program through compensation for cognitive skills.

THE ORIGIN: Medicare

To begin where payment for MTM originated on the large scale, it is appropriate to start with the Centers for Medicare and Medicaid Services (CMS). Medicare Part D patients have been the root in which a pharmacist and clinical compensation converge. Part of the Medicare Modernization Act (MMA) of 2003 established that Part D plans were required to embark upon MTM practices for cost control and quality improvement measures.

There have been various changes in CMS regulations over the years, including the most recent ones that occurred in 2010 with the introduction of the Affordable Care Act (ACA). These new revisions improved access to MTM for those eligible, amplified the intensity of interventions, altered requirements for explanation of benefits and defined parameters for comprehensive outcomes data collection.[1] MTM for the Medicare population continues to evolve as the services become understood and utilized by the beneficiaries.

Reimbursement for clinical services is achievable; however, it is neither simple nor entirely explicit.

The most important thing about requesting compensation for MTM services is to be persistent.

EVERY PLAN IS DIFFERENT: Seeking compensation for a Medicare Part D Patient

While MTM is a universally accepted model for Medicare Part D plans, each individual provider sets their own criteria in which patients are eligible for MTM, and most importantly to the pharmacist, what provider they will compensate for those services.

When determining which Part D beneficiaries are eligible, the various plans have criteria for whom to cover. For example, plans target patients with multiple chronic disease states (defined as any of two or more disease states), patients on multiple Part D covered medications (defined as any number greater than two) and patients who are likely to spend more than a set amount of money on medications in a year period.[2] However, this is where all simplicity and uniformity of coverage ends because the plans have various qualifications of how many medications as well as how many and which chronic disease states qualify. Each Part D beneficiary receives these qualifications in their benefits manual. In addition, if patients are eligible, they receive notification by various methods, such as mailings and (name another example of notification method), of their MTM eligibility.[1,2] All plans have their own restrictions concerning who can provide MTM to eligible patients. Often, the provider is an in-house or contracted MTM provider. However, there are plans that allow local community pharmacists to provide MTM to their local Part D patients. These plans require the pharmacist to contact their MTM service department to become a provider via established contracting channels.

Non Medicare Part D Compensation Opportunities

Current Procedural Terminology (CPT) codes are used for classifying and reporting services provided by health professionals. The American Medical Association has approved the following CPT codes for providing patients with Medication Therapy Management services:[3]

- 99605: First 15 minutes of an *initial or new patient* MTM face-to-face encounter provided by a pharmacist
- 99606: First 15 minutes of an *established patient* MTM face-to-face encounter provided by a pharmacist
- 99607: Used in conjunction with 99605 and 99606 for each additional 15 minutes spent with a patient providing MTM services

However, prior to submitting the first CMS-1500 form (previously referred to as HCFA-1500 form) for compensation there are a few key steps to complete.

First, obtain a National Provider Identification (NPI) Number. This is a fairly easy step and can be applied for by visiting the following website: *https://nppes.cms.hhs.gov/NPPES/Welcome.do.*

Once the NPI is obtained, it is important to contact the patient's medical insurance to receive an Insurance Provider Number to be able to bill for clinical services. For tips on this process, refer to "The Pharmacist's Guide to Compensation for Patient-Care Services".[4]

Filling out the CMS-1500 form may seem to be complicated, but there are multiple tools available in print and online to assist with the completion of this document. Although the form mostly requests patient information, field 24F requires the provider to list the charge for the service associated with the documented CPT code. In an effort to request an accurate amount for the services, it is important to research the market.

Expenses for consideration when calculating costs include salaries of the pharmacist and any allocated staff assisting with the program; necessary space and any remodeling costs; required startup materials and supplies, including items such as a laptop, printer, documentation system as well as ongoing purchases such as paper, ink cartridges, and blood glucose strips. It is also helpful to account for appropriate direct patient care equipment including scale, blood pressure cuff, and stethoscope. Finally, remember to include the cost of ongoing training and continuing education programs, as well as professional liability insurance for pharmacists. For a fee, online calculators are available to pharmacists to assist with the process, and an example can be found at the following website. *https://www.pharmaccount.com/Default.asp.*[3]

"Incident to" Billing Opportunities

If a pharmacist is currently employed by an ambulatory care clinic, "Incident to" documentation and billing are familiar terms, however, for many pharmacists "incident to" is an unfamiliar phrase. "Incident to" billing refers to reimbursing non-physician providers for services provided "incident to" a physician's care, including but not limited to, nurse practitioners, occupational therapists, respiratory therapists, social workers, audiologists, and pharmacists. Unlike billing for the MTM CPT codes, the pharmacist's services are billed under the physician's provider ID. Pharmacists partnering with physicians participating in medical home projects to provide MTM services to patients in the physician's office or clinic may consider "incident to" as a possible reimbursement option. [5,6]

The most important thing about requesting compensation for MTM services is to be persistent. Often, first attempts at billing using a platform database or CMS -1500 form are rejected. It is critical to reprocess and submit again, keeping in mind that multiple attempts may be required. While the process may be frustrating at first, it will be rewarding when receiving the first check in the mail. Good luck!

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For questions regarding MTM opportunities or suggestions, please contact MPhA Professional Development Committee Co-chairs Kristen M. Fink, PharmD, BCPS, CDE, Clinical Pharmacy Specialist, Kaiser Permanente and Fink's Pharmacy at fink462@hotmail.com or Hoai-An Truong, PharmD, MPH, Assistant Director of Experiential Learning at University of Maryland School of Pharmacy, and MTM Pharmacist at Mercy Health Clinic, Primary Care Coalition of Montgomery County, at htruong@rx.umaryland.edu.

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Epinephrine

By: David Chapdelaine, PharmD Candidate 2012

Regardless of the time of year, it is crucial for Americans to keep their epinephrine pens on hand. It is estimated that as many as 1 in every 100,000 individuals may be at risk for anaphylaxis and will need epinephrine in an emergency. Anaphylaxis is an allergic reaction by the body to triggers that can include food, bee stings, and medications. Without epinephrine on hand for injection into the bloodstream, this reaction can lead to difficulty breathing, swelling, loss of consciousness, or even death. Epinephrine was discovered in the 19th century through the hard work and collaborative effort of several scientists.

The Early Years

In 1891, Charles Brown-Sequard was the first to propose that ductless glands, such as the adrenal glands, may secrete substances into the bloodstream that have an effect in maintaining a normal state within an organism. Only three years later, in 1894, Dr. George Oliver and Dr. Edward Schafer produced an extract from the adrenal glands which was able to cause changes in the diameter of arteries in the human body. They later tested the extract in higher amounts in an un-anesthetized dog and found its powerful effects on altering blood pressure. In essence, they were the first to discover epinephrine's "Fight or Flight" capability, which leads to increased heart rate, blood pressure and energy for the body in emergency or alarming situations.

However, it was not until the work of Dr. John Abel and Dr. Jokichi Takamine isolated this first hormone, epinephrine. In 1897, while working as the chair of pharmacology at the Johns Hopkins Medical School, John Abel was able to isolate the hormone from the extract of sheep adrenal glands that Oliver and Schafer had earlier discovered. He went on to name this hormone extract 'epinephrin', which comes from the Greek terms epi meaning 'above' and nephros for kidney.

In the autumn of 1900, a Japanese chemist, Jokichi Takamine, visited Abel's laboratory and found that his isolation process was too complex and therefore needed simplification. Upon returning to his laboratory in New York City, Takamine did indeed purify Abel's extract, which was a benzoyl derivative of epinephrine. Takamine named this version of the extract, Adrenalin, and it was marketed by the pharmaceutical company Parke, Davis, and Company. Takamine claimed that his isolated compound had positive results in the treatment of acute conjunctivitis, diseases of the heart, diseases of the nose, as well as asthma, although there was no medical evidence obtained at the time. However, it was not until August of 1901 that Thomas Aldrich isolated Takamine's Adrenalin using a different purification method and was able to discover its true chemical formula.

Epinephrine Now

Today, epinephrine is used to relieve respiratory distress due to bronchospasm, relieve hypersensitivity to drugs or allergens, and to extend the action of anesthetics. Epinephrine has also played a key role in the discovery of autoreceptors in the human body, which in turn lead to the differentiation between adrenergic receptors on muscle and nerve cells. Although Able and Takamine did not realize it at the time, epinephrine was the first hormone to be discovered. Its unearthing was essential in the discovery of several other important catecholamines, like norepinephrine.

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TENTATIVE SCHEDULE OF EVENTS

7-8 a.m. *Registration & Continental Breakfast*

8-9:30 a.m. **New Drug Update**
Lynn McPherson, PharmD, BCPS, CDE
University of Maryland School of Pharmacy, Baltimore, MD

9:30 - 11 a.m. **How to Get Indicted by the DEA**
John Fader, RPh, Ret. Judge
University of Maryland School of Law
Baltimore, MD

11-11:15 a.m. *Break*

11:15-12:15 a.m. **TBA**
Joshua Scharfstein, MD, Secretary of the Maryland Department of Health and Mental Hygiene, Baltimore, MD

12:15-1:30 p.m. *Lunch and MPhA HOD Meeting*
OR *Lunch and MD-ASCP Meeting*

12:15-1:30 p.m. *Exhibits*

1:30-2:30 p.m. **Medicare Fraud**
Track 1 Capt. James Bresette, PharmD CMS
Baltimore, MD
OR

1:30-2:30 p.m. **Give Me Back Myself:**
Track 2 **2011 Alzheimer's Dementia**
David Jones, RPh, FASCP, Good Samaritan Hospital, Baltimore, MD
OR

1:30-2:30 p.m. **Pharmacy Law**
Technician Track Ashley McCabe, PharmD,
Catonsville Pharmacy, Catonsville, MD

2:30-3:30 p.m. **Assisted Living Facilities &Medication Therapy Management Update**
Track 1 Nicole Brandt, PharmD
University of Maryland School of Pharmacy
Baltimore, MD
OR

2:30-3:30 p.m. **Clinical Pearls**
Track 2 Nicholas Blanchard, PharmD
Dean University of Maryland
School of Pharmacy, Eastern Shore
Princess Anne, MD
OR

2:30-3:30 p.m. **Star Tech: To Boldly Go**
Technician Track Alisa Billington Morrison, PD
Consultant Pharmacist, Baltimore, MD
& David Jones, RPh, FASCP
Good Samaritan Hospital Baltimore, MD

3:30-3:45 p.m. *Break*

3:45-4:45 p.m. **Consultant Pharmacist 101**
Track 1 Eric Johnson, RPh, PD, FASCP
Independent Consultant Pharmacist
Columbia, MD
OR

3:45-4:45 p.m. **Woman's Health**
Track 2 Margee Parikh, PharmD, BCPS
Kaiser Permanente, Washington, DC
OR

3:45-4:45 p.m. **Pharmacy Calculations**
Technician Track Andy Michaelson, PharmD
Walgreens Pharmacy, Baltimore, MD

Early Bird Registration by Monday, January 30, 2012

This series, *Pharmacy and the Law*, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

Where Have You Gone Perry?

By Don. R. McGuire Jr., R.Ph., J.D.

Do you remember Perry Mason? How about Matlock? OK then, Denny Crane? Depending on your age, you should be familiar with at least one of these famous TV attorneys and their courtroom performances. This makes for entertaining TV, but in real life, the story is a little bit different. In most jurisdictions, the number of civil cases filed has been steady or increasing, but the number of trials has been decreasing. Why is this so?

The first reason is the discovery process. Discovery is the phase of the litigation process where the opponents share or exchange information and evidence. This includes documents, oral testimony (depositions), and written questions & answers (interrogatories). This exchange is mandated by the court rules. When discovery is complete, both parties should have all of the information that they need to evaluate the case and evaluate their chances of prevailing at trial. This typically makes at least one party reluctant to take the case to trial because they know what their chances are. No more surprise piece of evidence or last minute, surprise witness. These Perry Mason staples are virtually unheard of today. There are still some surprises at trial, but they tend to be smaller issues rather than earth-shattering ones.

The second reason is alternative dispute resolution (ADR). This ADR is different from the acronym that pharmacists are familiar with. ADR in the legal sense is a process of resolving cases without a trial. The most common forms are arbitration and mediation. In arbitration, the issues are presented to a neutral arbitrator who issues a ruling on the case. The process is greatly streamlined from that of a trial. For instance, in most cases, arbitration will not have live witness testimony. It is quicker and less expensive than a trial. The ruling can be binding or non-binding. In the non-binding situation, the parties can evaluate the ruling and compare it to their own predictions, but are not forced to accept it. Binding arbitration is considered a final ruling.

Mediation has no third party decision maker. A neutral mediator works to get both sides to agree to a mutually acceptable settlement of the case. The mediator does that by moving between the parties, sharing information where necessary, and listening to the strengths and weaknesses of each side. If no agreement is reached, the parties move on in the litigation process. Nothing that is said or offered at a mediation is admissible at trial, so parties are motivated to be as open and honest as possible with the mediator. In many jurisdictions, at least one round of ADR is required before any case can go to trial. It is not uncommon for a judge to order the parties to a second, or even a third, mediation.

In today's legal environment, the possibility, or desirability, of trial is quite different from TV lawyers. They try a case almost every week. Non-TV lawyers might have as few as two or three civil trials per year. Some commentators have actually expressed concern that we don't have enough trials. Case law is built on appellate decisions and with fewer trials, there are fewer appeals. But with all of our cards on the table and court rules that favor ADR, we shouldn't be surprised that there are more settlements and fewer trials. Maybe that is a good thing because it puts the parties in control of the ultimate resolution of their case and reduces the emotional toll on the parties. It won't be as entertaining to watch Matlock take more depositions.

© Don McGuire, R.Ph., J.D., is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

Shortages Bill: Warn FDA early

By Diane Yap

Proposing that prescription drug manufacturers warn FDA early about potential shortages, the Preserving Access to Life-Saving Medications Act is under consideration in the U.S. House of Representatives (H.R. 2245) and Senate (S. 296).

Early notice by drug manufacturers of a discontinuation or interruption in the manufacturing process would enable FDA "to work with other manufacturers to ramp up production," according to an American Society of Health-System Pharmacists (ASHP) issue paper. The Senate has formed a bipartisan working group and "similar efforts" are under way in the House.

Congressional Hearing

The Senate bill was referred to the Committee on Health, Education, Labor, and Pensions on February 7. The House bill was referred to the Committee on Energy and Commerce and then to the Subcommittee on Health. On September 23, the Subcommittee on Health held a hearing, Examining the Increase in Drug Shortages. Howard K. Koh, MD, MPH, Assistant Secretary for Health, U.S. Department of Health and Human Services, told the subcommittee that a drug shortage is defined by FDA as "a situation in which the total supply of all clinically interchangeable versions of an FDA-related drug is inadequate to meet the current or projected demand at the patient level." Koh's written testimony was posted on the committee website.

Koh discussed the importance of increased and earlier communications about drug shortages, according to Michael Spira, MA, APhA Senior Lobbyist, who attended the hearing.

The number of shortages is growing, Koh said, jumping from 61 in 2005 to 178 during 2010. The majority of drug shortages involve generic medications, and generic sterile injectables—such as oncology drugs—represent a large and increasing share of shortages.

According to Koh, drug shortages may be caused by factors including "industry consolidation, shortages of underlying raw materials, changes to inventory and distribution practices, difficulty in producing a given drug, quality and manufacturing problems, production, discontinuations for business reasons, and unanticipated increased demand."

FDA tracks shortages and uses "existing authorities and mechanisms" to work with manufacturers to prevent shortages, resulting in 38 prevented drug shortages in 2010 and 99 so far in 2011, Koh said.

Representing ASHP, Kevin J. Colgan, MA, FASHP, Corporate Director of Pharmacy, Rush University Medical Center in Chicago, told the subcommittee, "I am here today because I cannot serve my patients or their caregivers due to shortages of medications, some of them critical to patient care." He said ASHP supports the drug shortages legislation.

FDA Public Workshop

On September 26, FDA held a public workshop on drug shortages. The key message from the public workshop was that solutions for drug shortages need to come from all segments of the drug supply chain, not just FDA, Farah Towfic, PharmD, APhA Foundation Executive Resident, told *Pharmacy Today*. Towfic and Marcie Bough, PharmD, APhA Senior Director of Government Affairs, attended the meeting.

Bough reported that speakers at the meeting described a need for increased communication among manufacturers, FDA, wholesalers, and stakeholders; within a health care facility about what's on hand and what isn't; and about the extent of the shortages and when the drug will be available again.

Other takeaways, Bough said, were that efforts should be directed not just at preventing shortages, but also on better guidance, such as clinical guidelines, on alternative therapies. She also noted a focus on the need for consistent definitions for terminology used in discussions of shortages, and redundancy in manufacturer operations and efficiencies within FDA–manufacturer discussions.

Bough added that efforts to address drug shortage

issues and solutions may be discussed during reauthorization of the Prescription Drug User Fee Act (PDUFA) or other legislative vehicles. PDUFA IV, passed in 2007 as part of the FDA Amendments Act, expires in September 2012. While not every drug shortage can be prevented, congressional activity may help speed up potential ways of addressing them.

Organized Pharmacy

Among pharmacy organizations, ASHP takes the lead on drug shortages. APhA supports ASHP and FDA efforts to provide information on shortages. The House of Delegates will consider adopting formal policy on shortages at the 2012 APhA Annual Meeting & Exposition.

Independence of LTC Consultant Pharmacists Considered

Depicting the potential for a conflict of interest, CMS recently proposed a Medicare rule that considers requiring the independence of LTC consultant pharmacists from LTC pharmacies and drug manufacturers and distributors.

As considered, nursing homes also would be prohibited from contracting for consultant pharmacy services with an LTC pharmacy subsidiary created to provide reorganized services.

Appearing in the Federal Register on October 11, the proposed rule noted that LTC consultant pharmacists perform monthly drug regimen reviews for all residents, described payments from drug companies to LTC pharmacies and consultant pharmacists for encouraging physicians to prescribe the manufacturer's drugs for residents, and added that state laws or pharmacy boards may allow signed agreements under which consultant pharmacists can make medication switches.

"These types of arrangements may result in incentives for the LTC consultant pharmacist to make recommendations that conflict with the best interests of nursing home residents," CMS said.

Three LTC pharmacy organizations now have 90% of the market. CMS anticipates that consultant pharmacists may reorganize by becoming directly employed by nursing homes or "banding together" with other consultant pharmacists in professional corporations, aiming for an effective date of January 2013.

ASCP Reacts

The American Society of Consultant Pharmacists (ASCP) was aware that the agency was concerned about some areas of conflict of interest, but was not expecting the proposed rule, Lynne Batshon, ASCP Director of Policy & Advocacy, told *Pharmacy Today*. While the agency's examples of how there could be a potential for conflict of interest are accurate, she said, "We're concerned that the setting has not been portrayed accurately."

In a 2010 position statement, ASCP recommended that LTC consultant pharmacists should be independent of the LTC pharmacy providing medications to residents because of the potential for, or appearance of, conflicts of interest.

"I am deeply troubled that CMS has mischaracterized our profession by suggesting that consultant pharmacists don't serve patients' best interests as a primary goal of our practice," ASCP President Albert Barber, PharmD, CGP, FASCP, said in an ASCP news release, noting the ASCP Code of Ethics puts patients first.

To gather information, ASCP is conducting a survey and also is reaching out to member experts in a variety of settings with good data. Asked about the impact on consultant pharmacists, as considered, Batshon responded, "We are still in the process of evaluating that." As of October 13, ASCP had received nearly 1,200 responses, including from nonmembers. The reactions continue to pour in.

CMS requested comments be received by December 12, 2011. ASCP will submit comments to CMS. APhA will continue dialogue with ASCP and other pharmacy stakeholders as it analyzes and prepares comments on this issue and other provisions in the proposal.

REGULATORY SCORECARD:
What is Happening NOW!

Requests for information receiving public comments:

- FDA: Comments due by November 28 on draft guidance for industry on tablet scoring
- CMS: Comments due by December 12 on a proposed rule that seeks feedback on the independence of long-term care consultant pharmacists
- FDA: Comments due by December 23 on a September 26 drug shortages public workshop

Requests for information for which comment periods have closed:

- CMS: Resources and timelines necessary to implement a patient-centered approach to improving drug utilization controls in Part D
- CMS: Proposed rule that would enable patients to access their test results directly from labs

- ONC: Competition that challenges software developers to improve care transitions by developing technology that empowers discharged patients

Etc:

- FDA: A public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act by September 2012 was held on October 24.
- DEA: The latest National Prescription Drug Take Back Day was held October 29.
- For a complete list of all the issues and regulations being monitored and acted on by APhA, access the Government Affairs section of pharmacist.com. Also, print readers of the Hub should know that hyperlinks to pharmacist.com, Federal Register notices, and other useful websites can be accessed in the online version of the Hub, located at www.pharmacytoday.org.

Reprinted with permission from the Hub on Health Care Reform column in the November 2011 issue of *Pharmacy Today* (www.pharmacytoday.org). For more information about the Affordable Care Act and pharmacy's role in shaping the outcomes of this law, access the Government Affairs section of APhA's website, www.pharmacist.com.

Pharmacy Time Capsules

By: Dennis B. Worthen Lloyd Scholar, Lloyd Library and Museum, Cincinnati, OH

FOURTH QUARTER 2011

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: www.aihp.org

1986

Twenty-five years ago:

Food and Drug Administration approval of the first monoclonal antibody drug, Muronomab-CD3 (also known as Orthoclone OKT3), for treatment of transplant rejection.

Total health care expenses for a population of approximately 244 million were approximately $477 billion.

Average prescription price was $14.36 and the average number of new and refill prescriptions filled per year was 29,100 according to the *Lilly Digest*.

1961

Fifty years ago:

Pharmacist Donald Hedgpeth and the Northern California Pharmaceutical Association indicted for violation of the Sherman Anti-trust Act for the development of a pricing schedule that incorporated a professional fee.

Amitriptyline HCl (Elavil) was introduced in the US by Merck Sharp & Dohme.

Total health care expenses for a population of approximately 189 million were approximately $29 billion.

Average prescription price was $3.25 and the average number of new and refill prescriptions filled per year was 15,100 according to the *Lilly Digest*.

1886

One hundred twenty-five years ago:

The Brooklyn College of Pharmacy was formed in 1886. Renamed, it is now the Arnold and Marie Schwartz College of Pharmacy and Health Sciences of Long Island University.

Virtually All Your Expenses Are Optional

By Ric Edelman

George and Monica came to me several years ago. At the time, they had a combined annual income of $120,000, yet owed $22,000 to credit cards, and they were adding debt at the rate of $2,000 per month (they were obtaining a new card every month). Despite their high income, they were spending considerably more than they were earning.

When we reviewed their situation, I discovered that a lawn service visited their home twice a month, at $85 per visit. I told them to cancel the service, and George replied, "But our lawn will look terrible if we do that! We must keep this expense."

I also noticed that they subscribed to cable TV, including every premium channel—a monthly cost of $97! I told them to cancel cable. Monica gasped. "There will be nothing for us to watch! We can't cancel cable!"

I'm sure you'll agree with me that a lawn service and cable TV are optional, yet neither George nor Monica understood this. Both these expenses are optional, just as—pardon me for shocking you—virtually all your expenses are optional.

Health club membership? Optional.

Entertainment? Optional.

Telephone? Optional

Clothes? Most of it—or more accurately, the total money you spend on it—is optional. Food? Again, mostly optional. Oreos, I regret to inform you, are not mandatory.

Are you getting my point? Almost everything you spend money on is optional! So don't tell me, "I gotta do this, I gotta do that." Sometimes, though, you'll find that you've been spending money on a certain item or in a certain way for so long that by now, not only can't you remember when you didn't spend money like that, now you think you must. Again, let me repeat: Cable TV is optional. Hard to believe, but true.

You can stop spending your money on things that in the bigger picture really don't matter. You can change it. You can fix it. You can stop it.

You can stop spending your money on things that in the bigger picture really don't matter. You can change it. You can fix it.

Don't feel locked in or trapped, because you are not. True, there are some expenses that you cannot change easily or quickly. Once you buy a car, you're stuck with the payments. But most of your spending is much more flexible than you might think at first. You are in more control of what's happening around you than you realize. But you've been SNIOP'd for so long you've forgotten that you do have a choice about how you spend your money.

The bottom line is that you got into debt because of your attitude, not your income. And it is your attitude about money that must change first, or changes in income won't matter.

As it didn't for George and Monica. By refusing to change how they spent money, they sought other solutions for their debt. And they found one: the equity in their home. They owed $150,000 on their $200,000 home, so from the $50,000 in equity, they borrowed $25,000 and used that money to pay off their credit cards. Problem solved, right?

Wrong: Within a year, their credit card balances were back up to $24,000, only this time they no longer had $50,000 in home equity to rely on. Within two more years, unable to keep up with the payments on their house, they sold it and rented an apartment (at least that ended the lawn service). Still, it wasn't enough, and they later filed for bankruptcy. It will be 10 years before they are able to buy another house—if ever.

A Community Pharmacist's Approach for Identifying Unnecessary Drug Therapy in Medication Therapy Management

By Dennis E. Ferguson, BSP

INTRODUCTION:

With the implementation of Medicare Part D, the pharmacist's role in patient care, particularly in Medication Therapy Management (MTM), has been recognized by insurers providing Medicare Part D to their enrollees. One focus for patient care is the identification of unnecessary drug therapy. This article discusses how a community pharmacist identified an unnecessary use of a medication and made recommendations for a modification of the therapy.

Medication Therapy Management (MTM) can be used to focus on a patient's utilization of long term treatment for a specific condition. Recent reports in the medical literature have suggested that the chronic use of bisphosphonate therapy for osteoporosis may be interrupted for a nine to twelve month "drug holiday" if the patient has shown improved bone mineral density (BMD) after five years' therapy and does not present with a high risk for fracture. "In patients treated with bisphosphonate for several years, 1 year off the drug is not associated with an increase in vertebral fractures or hip fractures: 1 year would currently seem to be a reasonable duration for a drug holiday." [1] "Unnecessary therapy" is one focus of MTM which could be difficult for a community pharmacist. However, chronic bisphosphonate therapy is an easily identifiable treatment and, with a five year or greater medication history, a case can be made for identifying "unnecessary" bisphosphonate use.

A drug utilization review was conducted for patients taking Actonel, Fosamax and Fosamax-D, and its generic equivalent, alendronate. Since Boniva was not included in the studies reviewed, it was excluded from our review. We reviewed the usage of these medications from July 1, 2009 through February 4, 2010. This time period was selected to review current patients taking these medications. This eliminated patients whose therapy with these drugs has been discontinued. We then reviewed each individual patient for length of therapy, using five years as the minimum required length of treatment, and for compliance with that treatment. Since we are contracted to provide MTM services for CareFirst and Humana, participants in the Outcomes Program, we identified patients with CareFirst and Humana Medicare Part D plans who would be potential candidates for "drug holiday". Results of patients identified are shown in Table 1 (*next page*).

[1] Sebba A. Osteoporosis: how long should we treat? Current Opinion in Endocrinology, Diabetes & Obesity 2008;15:502-507.

TABLE 1

MEDICATION:	PATIENT TOTAL:	TOTAL ELIGIBLE:	CAREFIRST ELIGIBLE:	HUMANA ELIGIBLE:
Actonel 30 mg	2	1	0	0
Actonel 35 mg	40	20	1	1
Actonel 75 mg	1	1	1	0
Actonel 150 mg	2	1	1*	0
Fosamax 70 mg	3	3	1*	0
Fosamax D (2800)	14	3	0	0
Fosamax D (5600)	5	1	0	0
Alendronate 35 mg	11	1	0	0
Alendronate 70 mg	152	42	7	6
TOTALS:	230	73	9	7

Note: asterisk (*) represents patient duplication and is not included in totals.

DISCUSSION:

Of the 230 patients taking bisphosphonates, we determined that 73 (or 31.7%) had been taking these agents for over five years and were potential candidates for "drug holiday". Of these seventy-three, 16 patients were insured by either CareFirst or Humana, and they were contacted to see if they were interested in taking a "drug holiday" of one year if their prescriber approved.

Once the patients decided to take a "drug holiday", requests were faxed to their providers with follow-up telephone calls as necessary. (*See form letter, right*)

Of the sixteen patients, three did not take the "drug holiday":, one patient had already taken the 'holiday', and two patients were interested but the suggested "holiday" was rejected by the prescriber due to poor Dexascan results.

RESULTS:

Thirteen of sixteen potential candidates for a "drug holiday"

Dear Dr. _____

Recent literature suggests that women taking biphosphates for at least five years and are compliant with therapy may stop taking the medication for 9 to 12 months without increasing the risk of fractures. A similar effect may also apply to men. Additionally, fractures at unusual sites have been seem with long term biphosphonate therapy.

Your patient _____ expressed interest in withholding _____ for up to one year with follow-up bone density testing if you agree to this "drug holiday."

Thank you for considering this recommendation and please let us know if you decide to initiate the "drug holiday." If you have any questions please call Dennis Ferguson at 410-822-3700.

Sincerely,

Aleena S. Hassan
Student Pharmacist, Class of 2010

from their bisphosphonate therapy had their therapy placed on hold, a response rate of 81%. Using insurance payment data from the last time these patients received bisphosphonate medications, an estimated cost savings for the thirteen was approximately $10,500 of which 58% ($6,090) was in the patients' copay avoidance over the course of the year's "holiday". If these results were proportionately applied to the total remaining eligible population, total cost savings could theoretically approach $37,000. A more conservative estimate using only half of the remaining eligible patients would still yield a potential savings of $18-20,000. Pojected savings vary based on differences in the Medicare D plans' payment structures, variable deductibles, and "gap" payments.

The potential for cost avoidance for the Medicare Part D population served by our pharmacies could approach $37,000 per year.

CONCLUSION:

Patients enrolled in Humana and CareFirst Medicare Part D plans were identified for potential "drug holiday" from the bisphosphonates alendronate and risedronate. Of the sixteen patients identified as potentially eligible for the holiday, thirteen (81%) were able to take a year's holiday from their drug therapy, resulting in an approximated cost savings of $10,500 of which over half was in patient copay avoidance over the course of the holiday. None of the thirteen were restarted on their medications due to worsening of their osteoporosis and no fractures were reported during the one year "drug holiday."

The potential for cost avoidance for the entire Medicare Part D population served by our pharmacies could approach $37,000 per year.

The author would like to acknowledge the assistance of Aleena Hassan, PharmD, who at the time of the study was a PharmD candidate at the University of Maryland School of Pharmacy in Baltimore, Maryland and Katie Morneau, PharmD candidate, University of Maryland School of Pharmacy, who assisted in making follow-up calls to prescribers and patients at the conclusion of the study.

Recognizing Pharmacy Excellence

The 2012 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes individual professional excellence during the Annual MPhA Convention held in Ocean City, MD. To nominate a pharmacist for one of the awards described below, complete a Nomination Form and submit it to: Award Nominations, c/o Maryland Pharmacists Association, 1800 Washington Blvd., Suite 333, Baltimore, Maryland 21230-1701.

The Past Presidents Council reviews all nominations and is responsible for selecting award recipients. Upon selection, individuals will be notified in advance of the Annual Convention.

For consideration, all nominations must be received no later than **Friday, March 30, 2012**.

APhA Foundation & NASPA—Bowl of Hygeia Award

The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. *Who is Eligible:* Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

MPhA—Seidman Distinguished Achievement Award

Created by Henry Seidman to honor a Maryland pharmacist who has performed outstanding service over a number of years, and whose service has resulted in a major impact on the pharmacy profession. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria for the award.

Upsher Smith—Innovative Practice Award

Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria of the award.

Pharmacists Mutual—Distinguished Young Pharmacist Award

Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. *Who is Eligible:* Any MPhA pharmacist member who graduated from a school of pharmacy in 2002 or after.

MPhA—Mentor Award

This award recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria for the award.

MPhA—Honorary President

An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for MPhA or Maryland Pharmacy over a long period of time. *Who is Eligible:* Any long standing contributor to the profession or the Association.

APMS Partners with Cardinal Health Foundation— Cardinal Health Generation Rx Champions Award

This award honors a pharmacist who has demonstrated outstanding commitment to raising awareness of the dangers of prescription drug abuse among the general public and among the pharmacy community. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria for the award.

Nomination form on next page

MARYLAND PHARMACISTS ASSOCIATION | AWARD NOMINATION FORM

To nominate a Maryland pharmacist for one of MPhA's annual *Recognizing Pharmacy Excellence* awards, this form must be completed and returned to the Maryland Pharmacists Association no later than Friday, March 30, 2012. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please provide information as requested for each nominee and attach a current resume or a curriculum vita that demonstrates their professional and personal achievements. This information is essential for the Past Presidents Council to make their decision as to which candidates will be selected. In addition, a brief letter explaining why the nominee deserves to receive the award is requested.

☐ APhA Foundation & NASPA—Bowl of Hygeia Award

Nominee

Address

City, State & Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

☐ MPhA—Seidman Distinguished Achievement Award

Nominee

Address

City, State & Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

☐ Upsher Smith—Innovative Practice Award

Nominee

Address

City, State & Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

☐ Pharmacists Mutual—Distinguished Young Pharmacist Award

Nominee

Address

City, State & Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

☐ MPhA – Mentor Award

Nominee

Address

City, State & Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

☐ MPhA – Honorary President

Nominee

Address

City, State & Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

☐ APSM Partners with Cardinal Health Foundation—Cardinal Health Generation Rx Champions Award

Nominee

Address

City, State & Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

Return the completed form no later than Friday, March 30, 2012 to:

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Updated Clinical Practice Guidelines on the Management of Head Lice Infestation in Children

By Bik-Wai Bilvick Tai, PharmD Candidate and Donna Huynh, Assistant Professor,
University of Maryland School of Pharmacy

In August 2010, the American Academy of Pediatrics (AAP) released its newly updated clinical report on the treatment of head lice infestation in the pediatric population. First line recommended treatment options are available over-the-counter (OTC), therefore community pharmacists can play an active role in educating families about the management of head lice infestation. The objectives of this article are to review the treatment options for head lice and discuss important counseling points for various treatment options.

Head lice (pediculosis capitis) are parasitic insects that have been co-existing with human beings on Earth since ancient times.[1] In the United States, head lice infestation can affect all socioeconomic groups, but is most common among children between 3 to 12 years of age.[1] Head lice infestation causes limited morbidity but a great deal of anxiety among caregivers of school-aged children. Treatment costs associated with head lice infestation have recently been estimated to be $1 billion. [2] Head lice are not a health hazard or a sign of poor hygiene, and do not transmit or spread any diseases.[1] Although self-treatments with OTC pediculicide medications such as pyrethrin and permethrin are readily available, health care providers should be aware of the potential for misdiagnosis leading to the improper use of pediculicides.

An adult head louse is 2-3 mm long, has 6 legs, and is usually tan to grayish-white in color.[1] The gold standard for diagnosing head lice is to find a live louse on the head, which can be difficult since lice avoid light exposure and can crawl quickly. Previous studies have shown that diagnosis by using a louse comb is quicker and more efficient.[3] The tiny lice eggs may be easier to spot behind the ears and at the nape of the neck within 1 cm of the scalp.[1] It is essential to distinguish eggs or nits from hair casts, dandruff or hair debris to avoid misdiagnosis. It is also important not to confuse live eggs with dead or empty egg cases.

At room temperature, head lice usually cannot survive away from the scalp for more than one day. They can only crawl and never fly or hop. When found on combs, there is a great chance that the lice are either injured or dead. Except in situations where there is already a heavy infestation, healthy lice usually do not leave a healthy head. Since head lice transmission occurs via head-to-head direct contact, children should be told not to share personal items that come in contact with the head such as hats and combs.[1] Several OTC and prescription medications exist for the treatment of head lice infestation.

Permethrin, a synthetic pyrethroid, has been the most studied pediculicide in the U.S. and is also the least toxic to humans.[4] One percent permethrin lotion was approved for OTC use in 1990 and is marketed as a cream rinse. It is now one of the preferred drug treatments for head lice, and should only be considered for children who are aged more than 2 months.[5,6] To treat infestation, the product is applied to damp hair that is first shampooed with a non-conditioning shampoo and then towel dried. It is left on for 10 minutes and then rinsed off. Permethrin leaves a residue on the hair that is medically designed to kill nymphs. Nymphs are head lice that have hatched from the egg but have not yet reached adult stage.[1] However, this effect is mitigated with the use of conditioners and silicone based additives in shampoo.[1] It is recommended to repeat the application in 7 to 10 days if live lice are seen. Many experts now recommend routine re-treatment, preferably on day 9 due to the life cycle of the lice.[7,8] Reported adverse effects associated with use of permethrin include erythema, pruritus, and edema. Permethrin is less allergenic than pyrethrins, and does not cause allergic reactions in individuals with plant allergies. Resistance to 1% permethrin has been reported, but the prevalence of this resistance is not yet known.

Pyrethrins, another OTC pediculicide, are formulated with piperonyl butoxide. Pyrethrins are neurotoxic to lice but have extremely low toxicity to humans. Pyrethrins are made from natural extracts of chrysanthemum and,

therefore should be avoided in people with allergy to chrysanthemums. These products are available in shampoo or mousse formulations that are designed to be applied on dry hair and left on for 10 minutes before washing off with water. Hair should then be dried with a clean cloth and a fine tooth comb should be used to remain any nits. No residual pediculicidal activity remains after rinsing. Furthermore, none of these natural pyrethrins are completely ovicidal as 20 to 30% of the eggs remain viable after treatment, and this makes a second treatment necessary to kill newly emerged nymphs hatched from eggs that survived the first treatment.[1] Similar to permethrin, re-treatment at day 9 is considered optimal based on the life cycle of lice. Due to the development of resistance in recent years, the efficacy of this medication has declined sharply.[1] The resistance pattern seems to be highly variable across different communities and different countries.

Malathion, an organophosphate cholinesterase inhibitor, was reintroduced as a prescription-only 0.5% lotion for the head lice treatment in the U.S. in 1999 after being taken off the market twice. The current U.S. formulation of malathion (Ovide® lotion, 0.5%) is different from the malathion products in Europe that contain dipentene, terpineol, and pine needle oil, which also have pediculicidal properties9 and may delay the development of resistance. The product is applied to dry hair, left to air dry, then rinsed off after 8 to 12 hours. A fine tooth comb should be used to remove any nits. Malathion has high ovicidal activity, and a single application is appropriate for most patients. Reapplication of this product is deemed necessary in 7 to 9 days if live lice are still seen on head. This product contains a high alcohol content (i.e., 78% isopropyl alcohol) which is highly inflammable. Caregivers and patients should be educated to dry hair naturally and avoid the use of hair dryer, curling iron, or flat iron when the hair is wet. Caregivers should not smoke near a child who is receiving treatment. This product is contraindicated in patients younger than 2 years old.[1]

Benzyl alcohol 5% was, on the other hand, approved for the treatment of head lice in children older than 6 months in April 2009 by the U.S. Food and Drug Administration (FDA). This product is not neurotoxic and kills head lice by asphyxiation. The most common adverse reactions after treatment with benzyl alcohol include erythema, pyoderma, pruritus, and ocular irritation. The product is available by prescription only and is not ovicidal. According to package instructions, it should be applied to dry hair and allowed to soak for 10 minutes and be re-applied in 1 week.[10]

Lindane is no longer recommended for use as a pediculicide by the American Academy of Pediatrics (AAP),[11] and its use has been banned in state of California. It has been linked to several case reports of severe seizures in children and has relatively low ovicidal activity, with reported resistance development worldwide.[1] It is important to keep in mind that lindane is contraindicated in neonates, and extreme caution should be exercised when used in children and individuals who weigh less than 50 kg (110 lb), and in those who have HIV infection or take medications which can lower seizure threshold.[12]

In January 2011, FDA approved spinosad 0.9% topical suspension (Natroba™) for the treatment of head lice in children aged 4 years or older.[13] This prescription medication should be applied to dry hair and left on for 10 minutes before being rinsed off with warm water.13 The hair can be shampooed after the product has been rinsed off. Nit combing is not required after the use of this product.[13] Spinosad should be reapplied if live lice are seen after 7 days of treatment. Most common adverse effects were application site redness and eye redness and irritation 13 and, thus, it is important to counsel parents and caregiver to avoid contact with the eyes when applying this product. In two Phase 3 clinical studies, spinosad was found to be superior to permethrin in treating head lice.[13]

Other agents used off-label for the treatment of lice include topical scabicides such as 5% permethrin and 10% crotamiton, and oral agents such as ivermectin and sulfamethoxazole-trimethoprim. Both 5% permethrin and 10% crotamiton are available by prescription only. Ivermectin is an anthelmintic agent with a structure similar to macrolide antibiotics without antibacterial activity, and has been shown to be effective against head lice when administered with a single oral dose of 200 mcg/kg repeated once in 10 days.[14] Sulfamethoxazole-trimethoprim can cause Stevens-Johnson syndrome in rare cases so its use should be limited to patients who have failed first-line treatment with topical agents. All four products are not currently approved by the FDA for use as pediculicides. Natural products such as essential oils have been popular and widely used for self-treating head lice. However, they are not regulated by the FDA and do not have to meet FDA efficacy and safety standards for pharmaceuticals, therefore their constitutions as well as efficacies can change from product to product.

As a rule of thumb, all topical pediculicides should be rinsed off from the hair over a sink rather than in the shower or bath to reduce the likelihood of skin exposure, using warm instead of hot water to limit absorption due to vasodilatation of the skin.[1] Furthermore, after lice are

killed, mild burning and itching of the scalp can occur and persists for many days in response to topical medications. In this case, topical corticosteroids and oral antihistamines can be considered for relieving these signs and symptoms.[1]

When a diagnosis of head lice infestation is confirmed, self-care therapy could be initiated with OTC 1% permethrin or pyrethrins. If resistance to permethrin or pyrethrins is documented or treatments with these products fail to eliminate the head lice, prescription products should be considered.[1] Malathion 0.5% can be prescribed if the patient is over the age of 6, or benzyl alcohol 5% as an alternative therapeutic option if patient is older than 6 months. If the caregivers cannot afford or are not willing to use a pediculicide on their children, manual removal via wet combing, or an occlusive method, such as petroleum jelly or Cetaphil, can be suggested.[1] Referral to physician is considered when symptoms persist after home treatment, skin infection is suspected, or a certain prescription-only product is deemed necessary for individualized treatment.

There is no good way of preventing head lice infestation. However, since young children often have head-to-head contact with each other, it is essential to teach children not to share personal items such as combs, brushes, and hats with other people. When an individual is identified with head lice infestation, all household members should be checked for head lice. Those persons with live lice or nits within 1 cm of the scalp should be treated. Moreover, family members who share the same bed with the person with infestation are advised to receive treatment, even if no live lice are found. Only items that have been in contact with the head of the infested person within the 48 hour time period before treatment should be cleaned (e.g., hair care products, bedding, clothing, headgear, furniture, carpeting, and rugs). It is difficult for lice to survive off the scalp after 48 hours.[1]

During encounters with patients, pharmacists should make the best use of the counseling opportunity to instruct the patients or the caregivers on the selection, proper use, and possible side effects of different products. Because current products are not completely ovicidal, pharmacists should emphasize and advise the patients to apply the product twice at proper time intervals when permethrin or pyrethrin products are used or if live lice are seen after malathion therapy.[1] If patients have any inquires about head lice infestation, they can contact their health care providers, such as primary care physicians and pharmacists to obtain further information. Patient information materials concerning the diagnosis, treatment, and prevention of head lice are available at schools and local health departments, as well as from the official websites of various organizations such as the American Academy of Pediatrics, the National Pediculosis Association, and the Food and Drug Administration.

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Edited by Mary Lynn McPherson, Pharm.D., BCPS, CPE Professor, University of Maryland School of Pharmacy

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CONTINUING EDUCATION QUIZ

The Maryland Pharmacy Continuing Education Coordinating Council is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing education for pharmacists.

The questions below are taken from the article on *Updated Clinical Practice Guidelines on the Management of Head Lice Infestation in Children*. Circle the correct answer to each question and mail the entire page to: Maryland Pharmacist CE, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230-1701. There is no charge for this quiz for MPhA members; non-members should include a check in the amount of $10 made payable to MPhA. Program release date: October 15, 2011. Program expiration date: December 31, 2012. This program provides for 1.00 contact hour (0.1 CEU) of continuing education credit. A continuing education certificate will be sent to you within six to eight weeks. ACPE# 144-999-11-075-H01-P

NAME _____

ADDRESS _____

_____

CITY_____STATE_____ ZIP _____

DATE QUIZ COMPLETION _____

NABP E-PROFILE # _____

BIRTH DATE (MM/DD) _____

1. Which of the following is true about head lice?

a) Head lice infestation is most common among people between 14 to 22 years of age.
b) Head lice are responsible for transmitting or spreading diseases.
c) Adult head louse is 2-3 mm long, has 6 legs, and is usually tan to grayish-white color.
d) Besides crawling, head lice can also fly or hop.

2. Which of the following is true about permethrin?

a) It is one of the drugs of choice for head lice infestation.
b) Use of permethrin is commonly associated with adverse effects such as headache and otitis media.
c) To treat infestation, permethrin should be applied to dry hair and left to air dry.
d) Many experts now recommend one-time treatment to be sufficient for head lice infestation.

3. Which of the following product should be avoided in patients with HIV infection or history of seizure disorder?

a) 0.5% malathion
b) 5% benzyl alcohol
c) Lindane
d) Pyrethrins

4. Which of the following statement(s) is/are true?

1 Benzyl alcohol 5% is available in both OTC and prescription.
2 0.5% malathion should be applied to wet hair followed by manual removal using wet comb to treat head lice infestation.
3 Permethrin is less allergenic than pyrethrins, and can be safely used in patients with plant allergies.
4 Use of lindane is banned in state of California

a) Both 2 and 3 are true.
b) Both 3 and 4 are true.
c) 1, 3 and 4 are true.
d) All of the above are true.

5. If a child is diagnosed with head lice infestation, which of the following would be an appropriate action step?

a) OTC permethrin 1% or pyrethrins should be first attempted for treatment.
b) The child should still be allowed to share combs, brushes, and hats with other people.
c) Permethrin lotion should be applied after washing hair with conditioning shampoo with silicone-based additives to enhance its treatment effect.
d) Malathion 0.5% should be prescribed if the patient is 6 months old.

6. All of the following products are currently approved by FDA for use as pediculicides except which of the following?

a) Permethrin 1%
b) Malathion 0.5%
c) Benzyl alcohol 5%
d) Crotamiton 10 %

7. Concerning the use of topical medications for head lice treatment, which of the following is correct?

a) Ivermectin, which is a macrolide antibiotic, is shown effective against head lice when applied topically.
b) To limit absorption into the skin, all topical pediculicides should be rinsed off from hair over a sink with warm water.
c) Both formulations of 1% and 5% permethrin are currently considered as first-line topical therapies.
d) All currently approved topical pediculicides are ovicidal.

8. All household family members of a child diagnosed with head lice infestation

a) Should be checked for head lice.
b) Should receive treatment if they have shared the same bed with the diagnosed child.
c) Should understand that head lice are a sign of poor hygiene and a health hazard.
d) Only A and B are correct.
e) A, B, and C are correct.

9. Which of the following is true?

a) Prevention of head-to-head direct contact is a priority in head lice control activities.
b) Diagnosis of head lice using louse comb is the gold standard.
c) Sulfamethoxazole-trimethoprim should never be tried on patients with head lice infestation.
d) At present, resistance to topical prescription medication for head lice treatment has not been reported.

10. To properly use 1% permethrin for head lice treatment, it should be applied and left on hair for (1) before rising off with water, and is recommended for retreatment in (2) if lice still present.

	(1)	(2)
a)	5 mins	1- 2 days
b)	10 mins	1- 2 days
c)	10 mins	7- 10 days
d)	30 mins	7- 10 days
e)	60 mins	14 – 21 days

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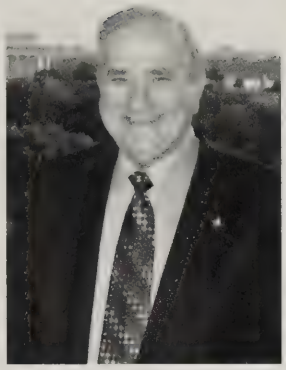

Howard Schiff
Executive Director

It's hard to believe that two years have passed since the sale of the former MPhA Headquarters, the Kelly Building, and our relocation to the Montgomery Park Business Center. It's very gratifying to see that the University of Maryland Medical Center Shock Trauma is putting the space to good use. At the same time it is amazing to see the huge building that now utilizes the entire footprint of our former property including the shrubbery, lawn, and driveway to the Emergency Room for their expansion.

The leasing of space for our current headquarters has relieved us from the chore of maintaining a stand-alone property. Even with the addition of an office for the new Assistant Executive Director Peggy Funk, we still have adequate space. In addition, our members and staff now enjoy free and secure parking (the building has 24/7 security). While the road construction on Washington Boulevard has been a challenge at times, we know that it can't last forever. We are thankful for the added luxury of a Conference Room that has made this venue into a true headquarters, available for use to all of our members. On occasion, the space been used to host receptions and provide networking opportunities for our student pharmacist members. Another amenity that we have at Montgomery Park is a large auditorium that the management company offers to tenants for free. This space was used for the very successful MTM Summit in March, and again for our Members Rewards Free CE in October of this year. Plans are in the works to use the auditorium again in the fall of 2012.

Montgomery Park has provided us with adequate space, convenient location, free and safe parking, and security. When our lease expires in five years a decision will have to be made to lease or buy. It will be incumbent on MPhA's decision makers to ensure that in selecting a new headquarters that the above criteria are considered. As always, I welcome members to provide suggestions and feedback for the committee. Have a safe and happy holiday.

Sincerely,
Howard Schiff
Executive Director

New Members

MPhA welcomes their newest Member Pharmacists

Barry Bress
Jeremy Cundiff
Benjamin Fawehinmi
Maria Johnson
Katie Klemm
Walter MacKay
Roy Mathew
Thomas Menighan
Ogechi Mezo
Lesley Navin
Godlove Ngunde
Sade Osotimehin
Folasade Osotimehin
Mohammad Rahman
Jaime Reid
Soumi Saha
Maxine Talbert
William Windham
William Zimmerman

MPhA
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Value Drugs

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Save the Dates

Sunday | February 12, 2012

MPhA/MD-ASCP Mid-Year Meeting
Conference Center at the Maritime Institute
Linthicum, MD

Featuring guest presenters Joshua Sharfstein, MD, Secretary of the Maryland Department of Health and Mental Hygiene and John Fader, RPh, Ret. Judge. Registration is now available online at **marylandpharmacist.org/**

Saturday-Tuesday | June 9 to June 12, 2012

130th Annual Convention
The Clarion Resort Fountainebleau Hotel
Ocean City, MD